

Johnson & Johnson: Promotion, Competition, and Medicine Access

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1. Executive assessment and the company being assessed

Johnson & Johnson's pharmaceutical history illustrates why drug-access reporting must distinguish three different questions: whether medicines are promoted appropriately, whether competitors can enter their markets, and what purchasers actually pay. This report examines documented United States enforcement involving Risperdal, Invega, and Natrecor, then considers more recent developments involving Stelara and Medicare negotiation. These episodes involve different products, business units, time periods, and legal standards. Combining them into one undifferentiated accusation would obscure rather than explain the evidence.

The contemporary company reports through Innovative Medicine and MedTech. Its former Consumer Health business was separated through Kenvue in 2023; Johnson & Johnson disposed of its remaining Kenvue shares in 2024. A consumer product bearing a familiar historical association should therefore not automatically be treated as a current Johnson & Johnson pharmaceutical product. The company's 2025 Form 10-K supplies the corporate boundary used here.¹

The most consequential historical finding in this review is the criminal component of the 2013 federal resolution. Janssen accepted responsibility for conduct described in a misdemeanor misbranding plea involving Risperdal. The much broader civil component resolved allegations and was not a judicial finding establishing every government contention. Johnson & Johnson expressly denied those civil allegations. Maintaining that distinction is essential even when the overall announced dollar amount is large.^{2,3}

Access also has a prospective dimension. FDA approval of a Stelara biosimilar, Medicare's negotiated-price program, and a 2026 antitrust filing concern routes through which competition or purchasing policy may change affordability. An approval demonstrates a regulatory determination; a negotiated price establishes a program-specific obligation; an amicus brief expresses a legal position. None, by itself, measures the number of patients who obtained medicine they previously could not afford.^{5,6,8}

Assessment. There is strong primary-source support for describing a serious historical promotional-compliance failure and significant public purchasing exposure. There is also a current, identifiable competition controversy. The evidence reviewed does not justify a company-wide estimate of price inflation, an assertion that every civil allegation was proved, or a claim that a percentage reduction from a published benchmark equals the same percentage reduction in each patient's bill. The useful transparency task is to make these boundaries visible alongside the substantive events, and then connect each proposed conclusion to the particular evidence capable of supporting it.

2. Historical context and a documented timeline

The Risperdal record developed through more than one proceeding. Janssen announced a roughly \$181 million consumer-protection settlement with 36 states and the District of Columbia in August 2012. Its announcement described the agreement as distinct from federal False Claims Act matters then under discussion, stated that the company admitted no wrongdoing, and said the parties did not characterize the payment as a fine or penalty.⁴ That description matters when constructing a timeline: a state consent resolution cannot simply be relabeled a federal criminal sentence.

In November 2013, DOJ announced a broader resolution exceeding \$2.2 billion. Its aggregate included \$485 million in criminal fines and forfeiture and \$1.72 billion in civil settlements. The announcement also included an earlier Texas payment within part of the civil total. Adding the headline amount to every previously reported payment would therefore risk double counting.²

Date	Documented development	Interpretation
August 2012	Multistate Risperdal consumer-protection agreement	Separate civil resolution; no admission
November 2013	Federal and state promotional-practices resolution	Criminal and civil components must be separated
October 2023	FDA approves Wezlana referencing Stelara	Regulatory competition milestone
January 2026	Initial Medicare negotiated prices take effect	Applies to eligible program transactions
June 2026	FTC files Stelara-related amicus brief	Legal argument, not a merits judgment

Sources: company statement, DOJ, FDA, CMS, and FTC.^{2,4,5,6,8}

The timeline does not imply a single continuing case from Risperdal to Stelara. The products differ, and a historical promotional resolution does not establish a later antitrust violation. Similarly, the 2023 biosimilar approval date should not be treated as the date on which every pharmacy stocked the medicine, every insurer covered it, or every patient could obtain it. Those are separate events requiring distribution and coverage evidence.

The conduct period, announcement date, legal instrument, and outcome are distinct parts of the historical record. This prevents a 2013 settlement from being presented as newly discovered misconduct in 2026. A subsequent court judgment could change the outcome of a disputed competition issue without changing the fact of the earlier filing. The chronology is therefore an organizing tool for accountability, not a scorecard that assigns equivalent meaning to every entry.

3. Principal evidence: what is established and what remains alleged

DOJ's 2013 materials describe a Risperdal criminal information addressing conduct during 2002-2003. Under the announced plea agreement, Janssen admitted promoting the medicine to providers for certain symptoms in elderly patients with dementia who did not have schizophrenia. The announced \$400 million Janssen criminal component comprised a \$334 million fine and \$66 million forfeiture. The announcement noted that court acceptance of the plea was still required at that point.² This report uses the announced agreement and admission; it does not invent a later sentencing date absent a reviewed judgment.

The company's contemporaneous account accepted accountability for the misdemeanor conduct while rejecting the civil allegations. It also said the resolution did not alter FDA approval for approved Risperdal indications and described a five-year corporate integrity agreement. Those statements do not erase the admitted conduct, but they constrain how the broader resolution should be characterized.³

There are two analytical distinctions. First, a manufacturer's promotional conduct and a clinician's prescribing decision are not interchangeable facts. A report about misbranding should identify the conduct the defendant admitted, rather than suggest that every patient receiving a medicine outside its original indication participated in wrongdoing. Second, a civil payment resolves exposure under a particular agreement; without a corresponding admission or adjudication, it is not proof of each allegation contained in a complaint. These distinctions improve both fairness and explanatory value.

The more recent Stelara matter is different. In June 2026, the FTC described a CareFirst class action alleging that Johnson & Johnson maintained monopoly power through acquiring Momenta Pharmaceuticals and using its patent portfolio to obstruct competition. The FTC's amicus argument concerned the legal standard for anticompetitive effects versus specific intent. It was not an agency order finding Johnson & Johnson liable, and the reviewed release did not supply a final merits disposition.⁸

The report therefore identifies a substantive competition question without answering it by assumption: did the challenged conduct impede rivals in a legally significant way? Answering that question requires the relevant market definition, challenged transactions and patents, evidence of competitive effects, defenses, and court rulings. A filing establishes that an issue is being contested. It cannot independently establish the amount of any overcharge or the duration of any unlawful delay. Those elements are distinct; the mere existence of litigation does not establish its result.

4. Pricing and access: interpreting the quantitative evidence

The monetary figures in the historical resolution are United States dollars paid or agreed under enforcement arrangements. They are not retail drug prices, estimates of excess profit, or direct measurements of injury. The approximately \$181 million state agreement and the later federal headline should not be aggregated without checking covered claims and prior payments. DOJ and the company used somewhat different headline scopes, which is another reason to retain the components and their source labels.^{2,3,4}

Medicare negotiation supplies a different kind of evidence. CMS published negotiated prices for the initial 2026 cycle, applicable from January 1, 2026, and estimated that applying those prices to 2023 utilization would have reduced net covered prescription costs across the ten selected drugs by about \$6 billion, or 22%. This was a retrospective model across the program's selected drugs, not observed Johnson & Johnson-specific savings. CMS separately projected beneficiary savings; that projection is not a count of people who gained access.⁶

Johnson & Johnson's implementation material identifies Xarelto, Stelara, and unbranded ustekinumab as affected medicines and describes systems for making the applicable price available through the program. The plan also discusses coordination with 340B pricing.⁷ These administrative details matter because an announced price must travel through a transaction process before it becomes meaningful to a dispensing pharmacy or eligible beneficiary. The existence of a workflow is evidence of implementation planning, not proof that every claim processed correctly.

A reproducible access analysis should distinguish four quantities: the manufacturer's published benchmark, the manufacturer's realized amount after concessions, the payer's reimbursed amount, and the patient's out-of-pocket charge. Comparing unlike quantities can produce an impressive percentage with little practical meaning. This report deliberately does not calculate a company-wide affordability improvement from mixed price series.

FDA's October 2023 Wezlana approval provides evidence of a potential alternative to Stelara. FDA found the biosimilar met applicable similarity and interchangeability standards; its announcement said such products may cost less.⁵ That statement is conditional. A follow-up study would need a defined product presentation, geography, coverage channel, observation period, and transaction price. It would also need to record unavailable prescriptions and rejected claims rather than only successful sales. A lower invoice price can coexist with access friction; conversely, a more expensive transaction can reflect a different dose or service. Separating these possibilities is more informative than inferring all access consequences from one price label.

5. Outcomes, company position, and current status

The historical outcome is a package of financial resolutions, a misdemeanor accountability component, and compliance commitments. Johnson & Johnson's November 2013 statement said the civil portion did not constitute an admission and emphasized continued research and the medicine's approved uses. Its earlier state-settlement statement similarly framed resolution as a way to avoid prolonged litigation.^{3,4} These are attributable company positions. They belong beside the government's account rather than being silently adopted or omitted.

The five-year duration of the integrity agreement is historical. It would be misleading to describe that specific agreement as a newly imposed or necessarily still-active 2026 restriction without separate evidence. Likewise, a completed settlement should not be described as an unresolved investigation merely because the source page remains online. Historical webpages preserve the language appropriate when they were issued; the report must supply the date and procedural context.

The 2025 annual-report materials describe continuing commercial growth and explicitly identify loss of Stelara exclusivity as a pressure on sales. The shareholder letter reports Innovative Medicine annual sales above \$60 billion and presents investment, approvals, and product development as central to the company's strategy.⁹ The report does not infer that all revenue growth results from higher prices or that lower revenue automatically represents patient savings. Revenue combines volume, product mix, geography, acquisition effects, exchange rates, and realized prices.

For Stelara competition, the latest specifically reviewed enforcement-related item is the FTC's June 2026 amicus release. It confirms a contemporary legal dispute, but not its eventual resolution.⁸ The September research check included searches for newer company and government material. No later merits judgment is asserted here. The procedural description is limited to the dated official material reviewed; a later docket entry or decision could supersede it.

For Medicare, the reviewed company implementation plan and CMS's published effective date support reporting that the initial-price cycle began in 2026.^{6,7} They do not constitute a postimplementation audit. The next useful evidence would be official transaction, compliance, or access reporting that measures what occurred after implementation. Until then, the defensible conclusion is narrower: the relevant obligation and operating framework exist, while the realized distribution of benefits requires additional observation. The report's public value lies in making the distinction between a promised mechanism, a legal requirement, and a measured outcome understandable.

6. Implications, methodology, and limitations

This is a new desk-research report, prepared for Pharma Foundation in September 2026. It is not a recovered historical paper, does not claim authorship by a previously named volunteer, and does not establish work completed before its preparation. The foundation's own activities and impact metrics are outside this company review. No private organizational records were needed to establish the public events discussed here.

The source set prioritizes contemporaneous DOJ material, FDA and CMS publications, the FTC's recent release, securities disclosures, and company responses. Each performs a different evidentiary function: a regulator describes its action; a company explains its position; a financial filing defines the reporting entity; and a policy document specifies a program. Agreement between two press releases is not an independent clinical or economic replication. Where the report offers an interpretation, it explains the comparison being made rather than presenting the interpretation as another official finding.

Three practical lessons follow from the reviewed material. First, accountability reporting needs procedural precision. “Charged,” “admitted,” “settled,” and “found liable” should never be interchangeable headline verbs. Second, medicine-access reporting needs a transaction definition. A drug name without strength, pack, date, country, and payer channel is insufficient for a meaningful price comparison. Third, competition reporting needs an observed pathway from regulatory authorization to market availability and coverage. Approval alone does not complete that pathway.

A stronger future quantitative study would select one medicine and one market, archive the relevant product identifiers and price sources, and calculate a transparent before-and-after series. It would describe missing data, inflation treatment, benefit-design changes, and potential confounding events. Patient-level results would require an appropriate, privacy-protecting dataset and a design capable of distinguishing association from causation. This report conducted none of those activities and reports no invented interviews, proprietary pricing database, clinical analysis, or causal estimate.

The substantive conclusion is therefore specific: Johnson & Johnson's record contains a documented historical promotional resolution with an admitted criminal component, separate civil settlements with expressly disputed allegations, and current policy and competition developments relevant to affordability. The proper next question is how those developments change actual access in identifiable settings. A transparent nonprofit report can ask that question firmly while preserving the boundaries of what its sources prove, allowing readers to inspect both the evidence and the remaining uncertainty.

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