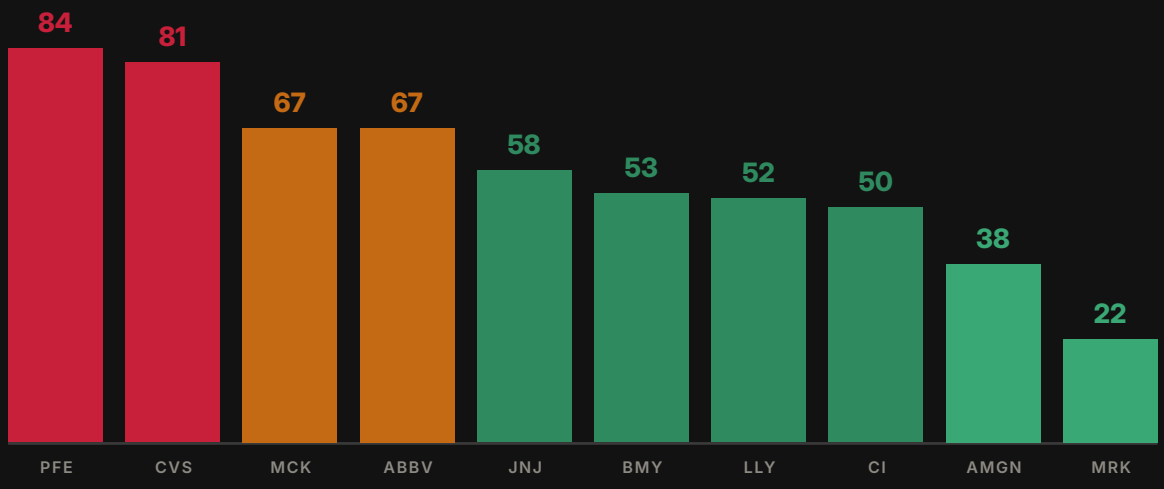
PRECEDENT
LAW, AS DECIDED

EDITION Q3 2026
Published 24 September 2026

FULL REPORT · PHARMACEUTICAL ENFORCEMENT · Q3 2026

RedFlag Index™

How the ten largest US pharmaceutical and healthcare companies rank on regulatory and enforcement exposure, with the record behind every score.



10	40	21	$7.9B
COMPANIES RANKED	DOCUMENTED CONTROVERSIES	OPEN MATTERS	LARGEST SETTLEMENT

PRECEDENT
LAW, AS DECIDED

Q3 2026 · FULL REPORT

Contents

01 **About the index** 03
Purpose, scope and score bands

02 **Methodology** 04
Six scoring factors and update cadence

03 **Rankings** 05
The Q3 2026 table

04 **Company profiles** 06
One page per company, with the full record

05 **Key findings** 17
Seven themes from the Q3 cycle

06 **RegulationWatch** 18
Enforcement timeline for indexed companies

07 **Definitions** 19
Terms used in this report

08 **Editorial standards** 20
Sources and corrections

IN THIS EDITION

84

Pfizer tops the index on the breadth of its open matters, from state COVID-19 vaccine suits to DOJ manufacturing inquiries.

$7.9B

McKesson's share of the national opioid distributor settlement, the largest single obligation in the index, paid over 18 years.

21

Open matters across the ten companies, with state attorneys general driving much of the new activity.

© 2026 The Precedent · Law, As Decided

01

About the index

The RedFlag Index™ is a composite 0 to 100 score measuring the cumulative regulatory and enforcement exposure of the ten largest publicly tracked US pharmaceutical and healthcare companies. Higher scores indicate greater exposure and a more adverse enforcement record.

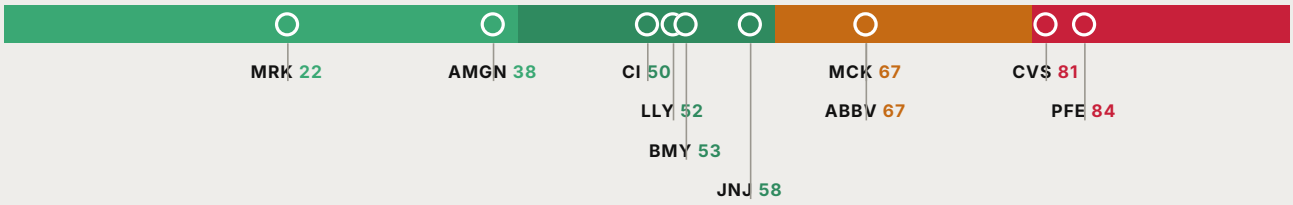
WHAT IT MEASURES

Settlements, judgments, consent orders, corporate integrity agreements and open investigations, drawn from DOJ, FTC, FDA, CMS, HHS-OIG, SEC and state attorney general records. Repeat conduct and litigation tactics that delay resolution count against a company.

WHO IT IS FOR

Investors, compliance teams, journalists and policymakers who need a consistent, sourced view of which companies carry the most enforcement risk and why. The index is not an endorsement and does not constitute legal advice.

WHERE THE TEN SIT · Q3 2026



0–39 · Lower
Limited verified enforcement in the review period

40–59 · Moderate
Notable historic record, recent activity limited

60–79 · Elevated
Significant settlement history, open investigations

80–100 · Critical
Active major enforcement, unresolved liabilities

CRITICAL	ELEVATED	MODERATE	LOWER	SPREAD, 1ST TO 10TH
2	2	4	2	62 pts

HOW TO READ THIS REPORT

Scores

Editorial judgments

Scores reflect The Precedent's assessment of public records. They are not legal determinations and are not shared with companies before publication.

Figures

As announced

Dollar amounts are those announced by regulators and courts. Where liability was not admitted, or a judgment is on appeal, the profile says so.

Open matters

Still unresolved

Active state AG suits, pending FTC proceedings and disclosed DOJ investigations that have not yet resolved.

Cadence

Quarterly review

All ten rankings are reviewed each quarter, and individual scores move whenever a company's record changes materially.

© 2026 The Precedent · Law, As Decided

02

Methodology

Scores are derived from six weighted factors applied to publicly verified enforcement records.

2.1

Settlement size

Dollar values of resolved federal and state enforcement actions, normalised to current-year terms. Criminal resolutions are weighted more heavily than civil settlements.

2.2

Recidivism

Repeat violations of substantially similar conduct, particularly under an existing CIA or consent decree, carry a significant multiplier.

2.3

Open investigations

Unresolved DOJ, FTC or state AG investigations are flagged as open controversies and scored on disclosed or estimated exposure.

2.4

Temporal decay

Actions older than five years contribute at reduced weight. Actions over ten years old are excluded unless directly relevant to an active matter.

2.5

Corporate integrity agreements

Active CIAs and consent orders with HHS-OIG, FTC or DOJ contribute for their full term.

2.6

Litigation posture

Appeals of adverse judgments, subsidiary bankruptcy to avoid mass tort liability and other conduct that delays resolution are aggravating factors.

Update cadence. Scores are updated when a covered company's enforcement record changes materially: on settlement announcement, consent order entry or final judgment. All ten rankings are reviewed quarterly regardless of new actions. Scores are not provided to covered companies before publication.

© 2026 The Precedent · Law, As Decided

03

Rankings · Q3 2026

#1 indicates the worst documented record. Score 0 to 100; higher is worse.

#	COMPANY	SCORE	BAND	CASES	OPEN
1	**Pfizer Inc.** PFE	84	CRITICAL	7	5
2	**CVS Health Corporation** CVS	81	CRITICAL	7	5
3	**McKesson Corporation** MCK	67	ELEVATED	3	1
4	**AbbVie Inc.** ABBV	67	ELEVATED	5	2
5	**Johnson & Johnson** JNJ	58	MODERATE	3	2
6	**Bristol-Myers Squibb Company** BMY	53	MODERATE	3	1
7	**Eli Lilly and Company** LLY	52	MODERATE	5	2
8	**The Cigna Group** CI	50	MODERATE	3	2
9	**Amgen Inc.** AMGN	38	LOWER	2	1
10	**Merck & Co., Inc.** MRK	22	LOWER	2	0

AVERAGE SCORE	MEDIAN SCORE	CONTROVERSIES	OPEN MATTERS
57.2	55.5	40	21

© 2026 The Precedent · Law, As Decided

04

Company profiles

One page per company, ranked from highest to lowest exposure. Each profile sets out why the company ranks where it does, the record behind the score, and what to watch next.

84 Pfizer Inc. — 07
Rank 01 · PFE · Critical

81 CVS Health Corporation — 08
Rank 02 · CVS · Critical

67 McKesson Corporation — 09
Rank 03 · MCK · Elevated

67 AbbVie Inc. — 10
Rank 04 · ABBV · Elevated

58 Johnson & Johnson — 11
Rank 05 · JNJ · Moderate

53 Bristol-Myers Squibb Company — 12
Rank 06 · BMY · Moderate

52 Eli Lilly and Company — 13
Rank 07 · LLY · Moderate

50 The Cigna Group — 14
Rank 08 · CI · Moderate

38 Amgen Inc. — 15
Rank 09 · AMGN · Lower

22 Merck & Co., Inc. — 16
Rank 10 · MRK · Lower

Reading a profile. Dollar amounts are as announced by regulators and courts. Where liability was not admitted, or a judgment is on appeal, the profile says so. Historical matters older than ten years are shown for context only and do not count toward the score.

© 2026 The Precedent · Law, As Decided

RANK 01 · PFE · COMPANY PROFILE

Pfizer Inc.

84
CRITICAL

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
84/100	7	5	$59.7M

WHY IT RANKS HERE

Pfizer tops the index on breadth rather than size. Its largest resolved matter in the review window is under $60 million, but it carries five open matters across federal and state jurisdictions, and much of its recent exposure arrived through acquisition, which the index treats as a recidivism factor.

THE RECORD

Biohaven and the Nurtec ODT speaker programmes

On January 24, 2025, Pfizer agreed to pay $59,746,277 on behalf of Biohaven to resolve allegations that, before Pfizer bought the company, Biohaven paid kickbacks through speaker programmes to induce prescriptions of its migraine drug Nurtec ODT between March 2020 and September 2022. The government alleged that some providers were paid tens of thousands of dollars, occasionally more than $100,000, and that events were attended by spouses, relatives and friends with no educational need. The settlement resolved a whistleblower suit by a former Biohaven sales representative; about $50.2 million went to the federal government and the rest to 38 states and Puerto Rico. Pfizer bought Biohaven for $11.6 billion in 2022. No liability was determined.

Kansas COVID-19 vaccine marketing suit

Kansas sued in Thomas County in June 2024 under the Kansas Consumer Protection Act, alleging Pfizer misrepresented the vaccine's safety and efficacy, including risks in pregnancy and of myocarditis, and that the conduct breached earlier consent judgments with the state. Pfizer removed the case to federal court, arguing the PREP Act pre-empted the claims. On May 14, 2025 Judge Daniel Crabtree sent it back to state court, holding that the claims concern deceptive marketing rather than physical injury.

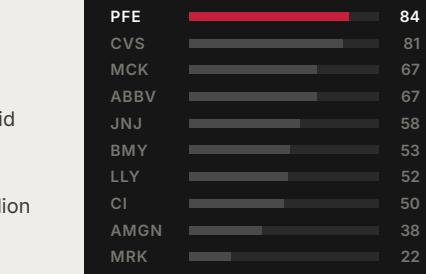
Texas COVID-19 vaccine marketing suit

Texas filed in November 2023 under the Deceptive Trade Practices Act, alleging Pfizer misrepresented its 95% efficacy figure and sought to suppress critics. After removal, Judge Sam Cummings dismissed the case on PREP Act immunity grounds on December 30, 2024. Texas appealed to the Fifth Circuit in January 2025, where judges at argument questioned whether the district court had jurisdiction at all. If they conclude it did not, the case returns to state court.

Disclosed investigations

Pfizer's June 2026 quarterly filing continued to disclose DOJ inquiries into manufacturing operations in India and two state attorney general complaints alleging generic-drug antitrust violations. Neither has resolved.

WHERE IT SITS



WHAT TO WATCH

- Fifth Circuit ruling on the Texas removal
- Kansas case in Thomas County
- DOJ India manufacturing inquiries

CONTEXT

Outside the ten-year window: Pfizer's 2009 $2.3 billion resolution over off-label promotion of Bextra, then a record.

SOURCES

DOJ and state AG releases; D. Kan. remand order; Pfizer Form 10-Q.

KEY MATTER	AMOUNT	DATE	STATUS
DOJ / Biohaven kickback settlement	$59.7M	Jan 24, 2025	**Resolved, no admission**
Kansas AG COVID-19 vaccine marketing suit	–	Remanded May 14, 2025	Active
Texas AG COVID-19 vaccine marketing suit	–	Dismissed Dec 30, 2024	On appeal (5th Cir.)
DOJ inquiries, India manufacturing operations	–	Disclosed Jun 2026	Open
Two state AG generic-drug antitrust complaints	–	Disclosed Jun 2026	Open

© 2026 The Precedent · Law, As Decided

RANK 02 · CVS · COMPANY PROFILE

CVS Health Corporation

81

CRITICAL

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
81/100	7	5	$948.8M

WHY IT RANKS HERE

CVS combines the largest dollar exposure in the index with the widest spread of conduct: retail dispensing, long-term care billing, and PBM pricing and rebates. Two 2025 False Claims Act judgments against its subsidiaries rank among the largest on record.

THE RECORD

Omnicare: dispensing without valid prescriptions

In April 2025 a jury found that Omnicare, CVS's long-term care pharmacy, submitted more than 3.3 million false claims to Medicare, Medicaid and TRICARE between 2010 and 2018 for drugs dispensed without valid prescriptions, and that CVS caused claims to be submitted. The case began with a 2015 whistleblower suit by an Omnicare pharmacist. In July 2025 the court entered judgment of $948.8 million, with CVS jointly liable for about $164.8 million. Omnicare filed for Chapter 11 two months later. Under a July 2026 deal the DOJ accepts at least $440 million, $130 million of it from CVS up front, with no admission of liability. The bankruptcy court approved Omnicare's plan in September 2026, alongside its sale to GenieRx.

Caremark: Part D price reporting

A former Aetna employee filed suit in 2014 alleging that Caremark caused Aetna and SilverScript to overstate drug costs to Medicare. The court found Caremark caused 513 false reports for 2013 and 2014, trebled $95 million in damages and on August 19, 2025 entered judgment of $289,873,500. CVS has appealed.

Insulin pens

In December 2025 CVS paid $37.76 million over allegations that from 2010 to 2020 its pharmacies under-reported days' supply and refilled insulin pens early, billing for more insulin than patients needed. CVS admitted certain of the conduct.

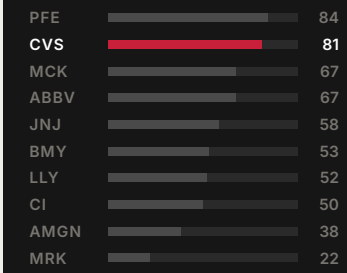
DOJ controlled-substances complaint

Unsealed in Rhode Island on December 18, 2024, the complaint alleges that since 2013 CVS knowingly filled unlawful prescriptions, including excessive opioid quantities, dangerous drug combinations and scripts from known pill-mill prescribers. CVS disputes the claims.

FTC insulin rebate case

On July 14, 2026 the FTC proposed consent terms with Caremark and its purchasing arm Zinc, mirroring the Express Scripts order. It estimates up to $8.5 billion in consumer savings over ten years. Public comment closed on September 4, 2026.

WHERE IT SITS



WHAT TO WATCH

- FTC decision on finalising the Caremark order
- Third Circuit ruling on the Caremark judgment
- Omnicare plan taking effect and GenieRx closing

CONTEXT

Also named in Texas's October 2024 insulin pricing suit and Oregon's $900 million insulin suit filed in January 2026.

SOURCES

DOJ (D.R.I., S.D.N.Y.) releases; E.D. Pa. and S.D.N.Y. judgments; N.D. Tex. bankruptcy filings; FTC Docket 9437.

KEY MATTER	AMOUNT	DATE	STATUS
Omnicare FCA judgment	$948.8M / $440M floor	Jul 2025 / Jul 2026	**Plan approved Sep 2026**
Caremark FCA judgment (Behnke)	$289.9M	Aug 19, 2025	On appeal (3rd Cir.)
Insulin-pen settlement	$37.76M	Dec 2025	**Resolved**
DOJ controlled-substances complaint	–	Dec 18, 2024	Active
FTC Caremark insulin rebate consent order	–	Jul 14, 2026	Pending finalisation
Texas AG insulin pricing suit	–	Oct 2024	Active

© 2026 The Precedent · Law, As Decided

RANK 03 · MCK · COMPANY PROFILE

McKesson Corporation

67

ELEVATED

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
67/100	3	1	~$7.9B

WHY IT RANKS HERE

McKesson has only three documented matters, but one is the largest single obligation in the index and the other two set a pattern. The company was penalised twice for the same failure, detecting and reporting suspicious controlled-substance orders, before the opioid crisis reached its national settlement.

THE RECORD

2008: the first suspicious-order agreement

McKesson agreed to a $13.25 million civil penalty and an administrative agreement with the DEA over failures to report suspicious orders of controlled substances. It then designed a compliance programme.

2017: the same failure, a record fine

In January 2017 McKesson paid $150 million, then the largest penalty in DEA history. The government alleged that between 2008 and 2013 it again failed to detect and report suspicious orders from independent and small-chain pharmacies while supplying rising volumes of oxycodone and hydrocodone, and that it had not fully implemented the programme built after 2008. Its Aurora, Colorado centre processed more than 1.6 million controlled-substance orders over five years and reported 16 as suspicious; the government alleged staff raised order thresholds to avoid reporting. The settlement suspended controlled-substance sales from centres in Colorado, Ohio, Michigan and Florida for several years and imposed five years of enhanced compliance under an independent monitor, the first in a Controlled Substances Act civil settlement.

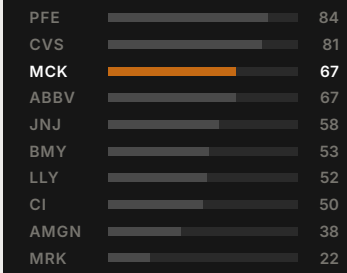
2022: the national distributor settlement

McKesson, Cardinal Health and AmerisourceBergen committed up to $21 billion, paid over 18 years, to resolve opioid claims by states and local governments. McKesson's share is about $7.9 billion. The settlement also carries injunctive terms governing how the distributors monitor and report orders.

2022: recordkeeping

Separately, the DOJ announced a $1 million Controlled Substances Act recordkeeping settlement with McKesson on March 14, 2022.

WHERE IT SITS



WHAT TO WATCH

- Annual opioid settlement payments
- Compliance with the settlement's injunctive monitoring terms

CONTEXT

The 2008 and 2017 resolutions fall outside or near the edge of the scoring window, but count toward the recidivism factor because the 2017 conduct repeated the 2008 failure.

SOURCES

DEA and DOJ releases (2008, 2017, 2022); national opioid settlement documents.

KEY MATTER	AMOUNT	DATE	STATUS
National opioid distributor settlement	~$7.9B	2022	**Payments over 18 years**
DOJ CSA recordkeeping settlement	$1M	Mar 14, 2022	**Resolved**
DEA / DOJ suspicious-order settlement	$150M	Jan 2017	**Resolved · recidivism factor**
DEA suspicious-order settlement	$13.25M	2008	**Resolved · recidivism factor**

© 2026 The Precedent · Law, As Decided

RANK 04 · ABBV · COMPANY PROFILE

AbbVie Inc.

67
ELEVATED

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
67/100	5	2	$2.37B

WHY IT RANKS HERE

AbbVie's score rests on Allergan's opioid obligations and on a new front in 340B pricing, where a March 2026 appeals ruling opened a route for False Claims Act suits against manufacturers that had not existed before.

THE RECORD

Allergan opioid settlement

AbbVie's Allergan unit agreed to a $2.37 billion national opioid settlement, announced in 2022 and finalised in 2023. Payment obligations remain active.

340B overcharging qui tam

In United States ex rel. Adventist Health System of West v. AbbVie, a covered hospital system alleges that AbbVie and three other manufacturers charged above the 340B ceiling price. The district court dismissed the case, but on March 17, 2026 the Ninth Circuit reversed, holding that the False Claims Act provides an independent route to such claims even though the 340B statute gives no private right of action. The court refused rehearing and rehearing en banc on May 28, 2026. The case returns to the district court, and the ruling exposes every manufacturer in the programme to similar suits in the Ninth Circuit.

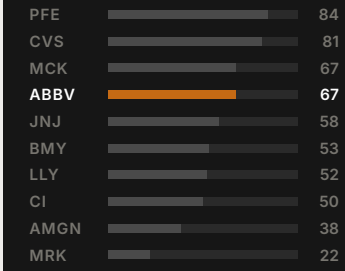
Humira marketing in California

In August 2020 AbbVie paid $24 million to California and a whistleblower to settle an insurance-fraud suit. The state alleged AbbVie gave physicians free professional services to induce Humira prescriptions and deployed nurse 'Ambassadors' who interfered with doctor-patient communication. AbbVie denied the allegations but agreed to disclose that it, not a medical provider, pays the nurses. The matter now carries reduced weight under temporal decay.

Promotional letters

FDA issued an untitled letter on Ubrelvy promotion in August 2024. AbbVie was also among the companies receiving multiple untitled letters in FDA's September 2025 crackdown on direct-to-consumer advertising.

WHERE IT SITS



WHAT TO WATCH

- District court proceedings in the Adventist 340B case
- AbbVie's pending IRA negotiation challenge
- Further 340B suits in the Ninth Circuit following the ruling

CONTEXT

Outside the ten-year window: predecessor Abbott Laboratories paid $1.5 billion in 2012 over off-label promotion of Depakote, before AbbVie's 2013 spin-off.

SOURCES

Ninth Circuit opinion No. 24-2180; California Department of Insurance release; FDA OPDP letters.

KEY MATTER	AMOUNT	DATE	STATUS
Allergan national opioid settlement	$2.37B	2022 / 2023	**Payments active**
340B qui tam (revived by 9th Cir.)	–	Mar 17, 2026	Active
California DOI Humira settlement	$24M	Aug 2020	**Resolved**
FDA untitled letter (Ubrelvy)	–	Aug 29, 2024	**Issued**

© 2026 The Precedent · Law, As Decided

RANK 05 · JNJ · COMPANY PROFILE

Johnson & Johnson

58

MODERATE

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
58/100	3	2	$1.64B

WHY IT RANKS HERE

J&J carries the largest False Claims Act judgment on record and a talc liability that three subsidiary bankruptcies failed to contain. Its score sits in the Moderate band because its biggest items are either under appeal or resolved marketing claims, but either could move it sharply.

THE RECORD

Janssen HIV drug judgment

Two former Janssen sales representatives sued in 2012, alleging off-label promotion of the HIV drugs Prezista and Intelence, including marketing Prezista as lipid-neutral contrary to its label. A jury found Janssen liable in June 2024 on the off-label claims but not the kickback claims. On March 28, 2025 Judge Zahid Quraishi entered judgment of $1.64 billion: $360 million in treble damages and $1.28 billion in penalties at $8,000 for each of 159,574 false claims. The Third Circuit heard Janssen's appeal in March 2026. Janssen argues the claims were not material to payment and challenges the constitutionality of whistleblower suits. Post-judgment interest continues to accrue.

Red River Talc

J&J's third attempt to resolve talc cancer claims through bankruptcy proposed a $9 billion trust, funded over 25 years, for roughly 90,000 gynaecological cancer claims. On March 31, 2025 Judge Christopher Lopez of the Southern District of Texas dismissed the case, citing irregularities in how votes were solicited and counted and releases for non-debtors that the Supreme Court's Purdue ruling does not permit. J&J said it would return to defending claims in the tort system.

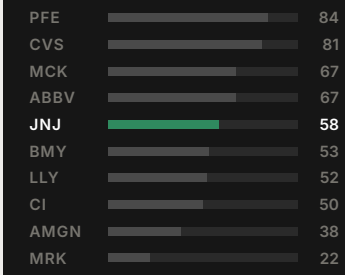
Talc marketing settlement

On June 11, 2024 J&J agreed to pay $700 million to 42 states and the District of Columbia over the marketing of talc-based baby and body powders. The consent judgments permanently bar it from making or selling talc powders in the US. There was no admission of liability, and the deal does not cover personal-injury claims.

Opioids

J&J committed up to $5 billion under the national opioid settlement implemented in 2022. Payment obligations remain active.

WHERE IT SITS



WHAT TO WATCH

- Third Circuit decision on the $1.64 billion Janssen judgment
- Talc personal-injury trials now back in the tort system
- IRA negotiation for Xarelto, Stelara and Imbruvica

CONTEXT

Outside the ten-year window: in 2013 J&J paid more than $2.2 billion to resolve criminal and civil allegations over Risperdal and other drugs, including a guilty plea by Janssen.

SOURCES

D.N.J. judgment; Third Circuit docket No. 25-1818; S.D. Tex. bankruptcy docket No. 24-90505; state AG releases.

KEY MATTER	AMOUNT	DATE	STATUS
Janssen FCA judgment (Prezista / Intelence)	$1.64B	Mar 28, 2025	On appeal (3rd Cir.)
Red River Talc bankruptcy	$9B plan rejected	Mar 31, 2025	**Dismissed; PI suits continue**
42-state + DC talc marketing settlement	$700M	Jun 11, 2024	**Resolved (marketing only)**
National opioid settlement (J&J share)	Up to $5B	2022	**Payments active**

© 2026 The Precedent · Law, As Decided

RANK 06 · BMY · COMPANY PROFILE

Bristol-Myers Squibb Company

53

MODERATE

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
53/100	3	1	$350M

WHY IT RANKS HERE

Bristol-Myers Squibb's record in the window is dominated by one state consumer-protection case that took more than a decade to resolve, together with continuing merger obligations. It has no open federal enforcement matter.

THE RECORD

Plavix in Hawaii

Hawaii sued BMS and Sanofi in 2014, alleging they failed to disclose that the blood thinner Plavix works less well, or not at all, in patients with a genetic variation in the liver enzyme that activates it, which is more common among people of East Asian and Pacific Islander descent. The state said the drug was prescribed more than 837,000 times in Hawaii between 1998 and 2010. After a bench trial the court awarded $834 million, raised to about $916 million on retrial in May 2024. The companies appealed, then settled on May 9, 2025 for $700 million split equally, with no admission of wrongdoing.

Celgene merger conditions

The FTC's order clearing the Celgene acquisition required BMS to divest the psoriasis drug Otezla, which went to Amgen for $13.4 billion, and imposes continuing obligations.

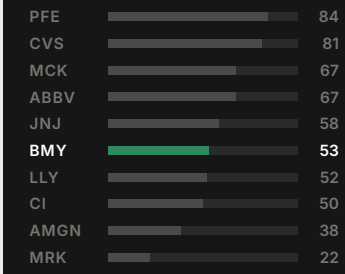
Medicare price negotiation

BMS challenged the IRA negotiation programme after Eliquis was selected in the first round. The Supreme Court declined to hear the case in May 2026, leaving lower-court rulings against the company in place.

Promotional letters

BMS was among the companies receiving untitled letters in FDA's September 2025 crackdown on direct-to-consumer advertising.

WHERE IT SITS



WHAT TO WATCH

- Compliance with the FTC Celgene order
- Negotiated Medicare prices for further BMS products

CONTEXT

Outside the ten-year window: in 2007 BMS paid $515 million to resolve allegations of off-label promotion and kickbacks.

SOURCES

Hawaii Governor and AG releases; FTC Celgene order; Supreme Court docket.

KEY MATTER	AMOUNT	DATE	STATUS
Hawaii Plavix consumer protection settlement	$350M (BMS share)	May 9, 2025	**Resolved**
FTC Celgene order (Otezla divestiture)	–	2020	**Continuing obligations**
IRA negotiation constitutional challenge	–	May 2026	**Cert denied**

© 2026 The Precedent · Law, As Decided

RANK 07 · LLY · COMPANY PROFILE

Eli Lilly and Company

52

MODERATE

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
52/100	5	2	$183.7M

WHY IT RANKS HERE

Lilly's five matters split between drug pricing and promotion. The Supreme Court's refusal to hear the Streck appeal in May 2026 turned a long-running dispute into a final adverse judgment, and Texas is pursuing Lilly on two separate fronts.

THE RECORD

Medicaid rebate judgment

A whistleblower sued in 2014 alleging Lilly concealed retroactive price increases and underpaid Medicaid rebates as a result. A jury found Lilly liable in August 2022; the award was trebled to $183.7 million. The Seventh Circuit affirmed in September 2025, finding ample evidence that Lilly chose to obscure rather than inquire. The Supreme Court denied certiorari on May 18, 2026. With interest the judgment now exceeds $220 million.

Texas kickback suit

In August 2025 Texas sued under its Health Care Program Fraud Prevention Act, alleging Lilly offered providers free nurses and reimbursement support to induce prescriptions of Mounjaro, Zepbound, Forteo and Verzenio, tainting Medicaid claims. The state alleges the nurses took on low-reimbursement follow-up work so that practices could see more patients.

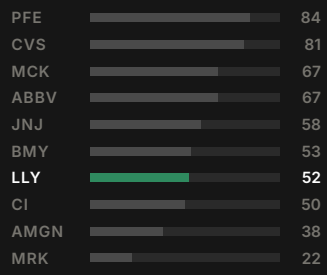
FDA warning letters

On September 9, 2025 FDA issued Lilly three warning letters over tirzepatide promotion: two for online videos on local news websites and one for material aired in a television special on GLP-1 drugs. The letters formed part of FDA's broader crackdown on direct-to-consumer advertising.

Insulin pricing

Lilly is a defendant in Texas's October 2024 insulin pricing suit and Oregon's $900 million suit filed in January 2026. In February 2024 it settled with Minnesota, agreeing to cap insulin at $35 a month for eligible residents and donate insulin to clinics, with no monetary penalty and no admission.

WHERE IT SITS



WHAT TO WATCH

- Proceedings in the Texas kickback suit
- Texas and Oregon insulin pricing cases
- Follow-up to the September 2025 FDA letters

CONTEXT

Outside the ten-year window: in 2009 Lilly paid $1.415 billion and pleaded guilty over off-label promotion of Zyprexa.

SOURCES

N.D. Ill. judgment; Seventh Circuit opinion; Supreme Court docket; Texas AG filing; FDA warning letters.

KEY MATTER	AMOUNT	DATE	STATUS
Medicaid rebate FCA judgment (Streck)	$183.7M (>$220M w/ interest)	May 18, 2026	**Final; cert denied**
Texas AG kickback suit	–	Aug 2025	Active
FDA warning letters (x3, tirzepatide)	–	Sep 9, 2025	**Issued**
Texas AG insulin pricing suit	–	Oct 2024	Active
Minnesota insulin pricing settlement	No monetary penalty	Feb 7, 2024	**Resolved**

© 2026 The Precedent · Law, As Decided

RANK 08 · CI · COMPANY PROFILE

The Cigna Group

50

MODERATE

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
50/100	3	2	$172.3M

WHY IT RANKS HERE

Cigna sits in the Moderate band but has the fastest-growing docket in the index. Its Express Scripts unit has picked up new state actions in Michigan, Florida and Louisiana since April 2025, most of them targeting the same 2019 arrangement with a rival PBM.

THE RECORD

Medicare Advantage diagnosis codes

On September 30, 2023 Cigna agreed to pay $172,294,350 to resolve allegations that it submitted, and failed to withdraw, unsupported diagnosis codes to inflate Medicare Advantage payments. The DOJ alleged many diagnoses came from in-home assessments by nurse practitioners that were designed to capture codes rather than treat patients, and that serious conditions were recorded without the testing needed to support them. Cigna entered a five-year corporate integrity agreement.

FTC insulin rebate order

On February 4, 2026 the FTC settled its case against Express Scripts. The FTC expects the terms, which delink PBM pay from list prices and require net-cost formulary options, to cut patients' out-of-pocket costs by up to $7 billion over ten years. The respondents denied the charges.

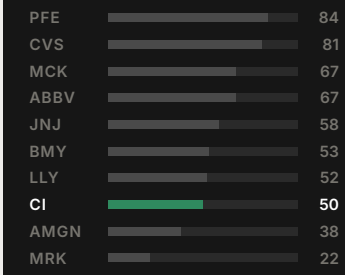
State antitrust suits

Michigan sued Express Scripts and Prime Therapeutics in April 2025, alleging their 2019 collaboration fixed pharmacy reimbursement rates. Florida filed on similar grounds on August 27, 2026, and Louisiana sued Express Scripts and its affiliate Ascent Health Services in federal court on August 31, 2026, alleging patient steering, reimbursement manipulation and the same agreement with Prime. Louisiana says Express Scripts manages prescriptions for about 71% of its residents.

Kentucky and Arkansas

On September 18, 2026 the Sixth Circuit kept Kentucky's opioid suit against Express Scripts and OptumRx in federal court, reversing a remand. Separately, twelve Arkansas pharmacies filed a private suit in Missouri state court on September 15, 2026, alleging reimbursements below Arkansas's statutory floor.

WHERE IT SITS



WHAT TO WATCH

- Michigan, Florida and Louisiana antitrust cases
- Kentucky opioid case proceeding in federal court
- Compliance under the FTC order and the CIA

CONTEXT

Express Scripts is also a defendant in Texas's 2024 insulin pricing suit and Oregon's January 2026 insulin suit.

SOURCES

DOJ (E.D. Pa., S.D.N.Y.) releases; FTC release; Michigan, Florida and Louisiana AG filings; Sixth Circuit docket.

KEY MATTER	AMOUNT	DATE	STATUS
Medicare Advantage FCA settlement + CIA	$172.3M	Sep 30, 2023	**Resolved; CIA active**
FTC Express Scripts insulin rebate order	–	Feb 4, 2026	**In force**
Michigan / Florida antitrust suits (ESI / Prime)	–	Apr 2025 / Aug 2026	**Active**
Louisiana antitrust suit (ESI / Ascent)	–	Aug 31, 2026	**Active**
Kentucky opioid suit	–	Sep 18, 2026	**Active; federal court**
Arkansas pharmacies' reimbursement suit (private)	–	Sep 15, 2026	**Active**

© 2026 The Precedent · Law, As Decided

RANK 09 · AMGN · COMPANY PROFILE

Amgen Inc.

38
LOWER

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
38/100	2	1	$24.75M

WHY IT RANKS HERE

Amgen's low score reflects a thin enforcement record in the window. Its principal exposure is a set of conduct restrictions attached to a merger, not a finding of misconduct.

THE RECORD

Horizon Therapeutics merger order

The FTC and six states sued in May 2023 to block Amgen's $27.8 billion acquisition of Horizon, arguing Amgen could bundle rebates on its blockbusters to entrench Horizon's Tepezza and Krystexxa. The case settled, and the final order entered on December 13, 2023 bars bundling and rebate conditions involving the two drugs, requires prior approval for certain acquisitions, and runs for 15 years under an FTC-appointed monitor. Amgen denied the alleged violations.

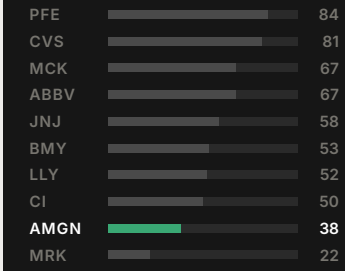
Copay charities

In 2019 Amgen paid $24.75 million to resolve DOJ allegations that it used independent charities as conduits to cover Medicare patients' copays for its own drugs, an arrangement the government treats as a kickback. The matter now carries reduced weight under temporal decay.

Otezla

Amgen bought Otezla for $13.4 billion when the FTC required Bristol-Myers Squibb to divest it as a condition of the Celgene deal.

WHERE IT SITS



WHAT TO WATCH

- Monitor reporting under the Horizon order
- Negotiated Medicare pricing for Enbrel

CONTEXT

Outside the ten-year window: in 2012 Amgen paid $762 million and pleaded guilty over the promotion of Aranesp.

SOURCES

FTC Horizon order; DOJ release (2019).

KEY MATTER	AMOUNT	DATE	STATUS
FTC Horizon acquisition consent order	–	Dec 13, 2023	**15-yr obligations, monitor**
DOJ Medicare copay charity settlement	$24.75M	2019	**Resolved**

© 2026 The Precedent · Law, As Decided

RANK 10 · MRK · COMPANY PROFILE

Merck & Co., Inc.

22

LOWER

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
22/100	2	0	$16.7M

WHY IT RANKS HERE

Merck ranks last. It has no open enforcement matter, no federal criminal resolution since 2015, and its most prominent recent litigation is a case it brought against the government.

THE RECORD

IRA negotiation challenge

Merck was the first drugmaker to sue over Medicare price negotiation, filing in June 2023 after signalling that Januvia would be selected. On August 24, 2026 Judge Colleen Kollar-Kotelly rejected its First and Fifth Amendment claims and granted judgment to the government. The ruling imposed no penalty. Januvia's negotiated price took effect on January 1, 2026; Janumet follows in 2027 and Lenvima in 2028, and Merck expects Keytruda to be selected in 2027.

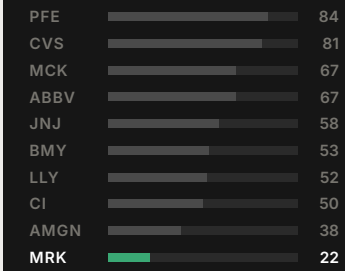
Animal Health promotion

FDA issued an untitled letter to Merck Animal Health on May 14, 2026 concerning promotion of Bravecto Quantum.

Vioxx state settlements

In 2016 Merck settled consumer-protection claims over Vioxx with Alaska for $15.25 million and Montana for $16.7 million. Both now carry reduced weight under temporal decay.

WHERE IT SITS



WHAT TO WATCH

- Any appeal of the August 2026 IRA ruling
- Keytruda's expected selection for negotiation in 2027

CONTEXT

Outside the ten-year window: in 2011 Merck paid $950 million and pleaded guilty over the promotion of Vioxx.

SOURCES

D.D.C. ruling; Merck Form 10-Q; FDA OPDP letter; Alaska and Montana AG releases.

KEY MATTER	AMOUNT	DATE	STATUS
IRA negotiation constitutional challenge	–	Aug 24, 2026	**Rejected**
FDA untitled letter (Bravecto Quantum)	–	May 14, 2026	**Issued**
Vioxx state settlements (AK, MT)	$15.25M / $16.7M	2016	**Resolved**

© 2026 The Precedent · Law, As Decided

05

Key findings

Seven themes from the Q3 2026 review cycle.

01 PBM sector dominates the enforcement landscape

Three of the top eight RedFlag companies have significant pharmacy benefit manager exposure. The FTC's September 2024 administrative case against the three largest PBMs, Caremark (CVS), Express Scripts (Cigna) and OptumRx (UnitedHealth), produced consent orders with the first two in 2026. The structural remedy, delinking PBM compensation from list price and requiring net-cost formulary options, is the most sweeping regulatory restructuring of the PBM sector in its history.

02 Pfizer leads on recidivism-weighted exposure

Pfizer holds the top position not because of a single catastrophic resolution but because of the breadth and recency of its open matters: active COVID-19 vaccine suits in Kansas and Texas, open DOJ manufacturing inquiries and ongoing generic antitrust proceedings. The Biohaven settlement adds to a pattern of enforcement inherited through acquisitions, a structural risk the index treats as a recidivism factor.

03 CVS Health carries the highest raw dollar exposure

CVS's aggregate resolved and proposed dollar exposure in the current review period exceeds $1.7 billion across the Omnicare FCA judgment, the Caremark FCA judgment, the insulin-pen settlement and the Caremark FTC consent order. No other indexed company approaches this level of dollar-denominated exposure in a single review cycle.

04 Opioid settlement obligations persist

McKesson (rank 3) and AbbVie/Allergan (rank 4) both carry active multi-billion dollar opioid settlement obligations. McKesson's ~$7.9 billion share of the national distributor settlement is paid over 18 years. These are ongoing financial and compliance obligations, and they continue to weigh on each company's score.

05 J&J's talc bankruptcy strategy has failed

Johnson & Johnson's three attempts to resolve talc personal-injury liability through subsidiary bankruptcy have all been dismissed, most recently Red River Talc on March 31, 2025. More than 50,000 individual claims remain in the tort system. The $1.64 billion Janssen HIV drug judgment is on appeal at the Third Circuit and continues to accrue post-judgment interest.

06 Medicare price negotiation challenges uniformly failing

Merck, J&J, Bristol-Myers Squibb, Novo Nordisk, Novartis, Boehringer Ingelheim and AstraZeneca have all seen their constitutional challenges to IRA negotiation rejected by federal courts or denied certiorari. Merck's challenge, the first filed, was rejected on August 24, 2026. AbbVie and PhRMA challenges remain pending.

07 State enforcement accelerating

Q3 2026 saw Louisiana's antitrust suit against Express Scripts (August 31), an Arkansas pharmacy reimbursement suit against Express Scripts (September 15) and the Sixth Circuit's retention of Kentucky's opioid PBM case in federal court (September 18). The Texas AG's insulin pricing and kickback actions against Lilly and CVS continue.

© 2026 The Precedent · Law, As Decided

06

RegulationWatch

Selected enforcement reporting involving indexed companies, most recent first.

Sep 18, 2026	DRUG PRICING	Arkansas pharmacies sue Express Scripts over reimbursement floor	CI
Sep 18, 2026	PBM REBATES	Sixth Circuit keeps Kentucky opioid case against PBMs in federal court	CI
Aug 31, 2026	PBM REBATES	Louisiana files federal antitrust suit against Express Scripts and Ascent	CI
Aug 27, 2026	ANTITRUST	Florida sues Prime Therapeutics and Express Scripts over alleged price-fixing	CI
Aug 24, 2026	DRUG PRICING	Federal judge rejects Merck's IRA negotiation challenge	MRK
Jul 14, 2026	PBM REBATES	CVS Caremark becomes second major PBM to settle FTC insulin case	CVS
May 18, 2026	MEDICARE NEGOTIATION	Supreme Court declines drugmaker appeals on Medicare negotiation	BMY · LLY
Feb 4, 2026	FTC ENFORCEMENT	FTC settles insulin rebate case with Express Scripts	CI
Jan 15, 2026	PBM REBATES	Missouri sues 19 PBMs and insulin makers over pricing scheme	Multiple
Jan 7, 2026	DRUG PRICING	Oregon seeks $900M from insulin makers and PBMs	LLY · CI · CVS
Jan 24, 2025	FALSE CLAIMS ACT	Pfizer pays $59.7M over Biohaven Nurtec kickbacks	PFE
Jun 11, 2024	STATE ENFORCEMENT	J&J pays $700M to states over talc powder marketing	JNJ
Feb 7, 2024	DRUG PRICING	Lilly settles with Minnesota to cap insulin at $35	LLY
Dec 13, 2023	MERGER CONDITIONS	Amgen bound by FTC bundling ban from Horizon deal	AMGN

© 2026 The Precedent · Law, As Decided

07

Definitions

False Claims Act (FCA)

A federal statute, 31 U.S.C. §§ 3729–3733, imposing civil liability on persons and companies that defraud federal programmes. Violators face treble damages plus per-claim penalties; qui tam provisions let private relators sue on the government's behalf.

Corporate Integrity Agreement (CIA)

A compliance agreement with HHS-OIG, typically entered alongside civil settlement of healthcare fraud allegations. Requires independent monitoring and compliance reporting, usually for five years.

Consent Order

An agreement with a regulator, most often the FTC, resolving an investigation without admission of liability. Conduct restrictions are enforceable as court orders.

Pharmacy Benefit Manager (PBM)

An intermediary administering prescription drug benefits. The three largest, OptumRx, Express Scripts and Caremark, process the majority of US retail prescriptions.

Qui Tam

A provision of the FCA allowing a private relator to file a sealed complaint on the government's behalf and receive 15 to 30% of any recovery.

Formulary

The list of drugs covered by a health plan or PBM. Placement and tier determine patient costs and influence prescribing.

Medicare Part D

The federal prescription drug benefit, administered through private insurers that contract with PBMs.

340B Program

A federal programme requiring manufacturers to provide outpatient drugs to covered entities at reduced prices. Contract-pharmacy restrictions have generated active litigation.

IRA Negotiation

Provisions of the Inflation Reduction Act of 2022 (42 U.S.C. § 1320f) authorising CMS to negotiate prices for high-spend Medicare drugs.

Open Controversy

An enforcement action, investigation or litigation not yet resolved, including disclosed DOJ civil investigative demands, active state AG suits and pending FTC proceedings.

Recidivism

Conduct substantially similar to that of a prior enforcement action, particularly while operating under an existing CIA, consent order or settlement.

© 2026 The Precedent · Law, As Decided

08

Editorial standards

All enforcement actions, settlements and judgments documented in this index are drawn from primary sources.

Sources include DOJ press releases and settlement agreements, court dockets, FTC orders, FDA enforcement letters and state attorney general announcements. Dollar amounts reflect announced figures. Where liability has not been admitted, this is noted. Where a judgment is on appeal, this is noted. The Precedent does not independently verify the merits of underlying allegations; we document what regulators and courts have found or alleged.

Scores are editorial judgments based on public records. They are not legal determinations. Companies are invited to submit factual corrections before publication; verified corrections are incorporated. This report reflects the index as of September 24, 2026.

> **Submit a tip or correction** at theprecedent.org · Follow @theprecedentX

© 2026 The Precedent · Law, As Decided

PRECEDENT

LAW, AS DECIDED

Independent regulatory intelligence covering accountability in the US pharmaceutical industry.

© 2026 The Precedent · Law, As Decided