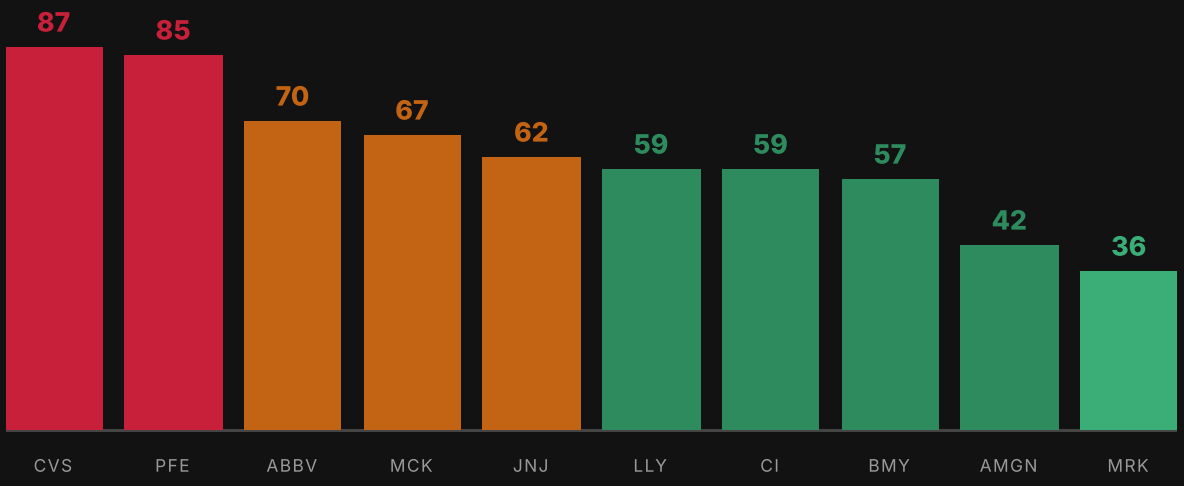
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EDITION NOVEMBER 2026
Published November 2026

FULL REPORT · PHARMACEUTICAL ENFORCEMENT · NOVEMBER 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	54	32	$7.9B
COMPANIES RANKED	DOCUMENTED CONTROVERSIES	OPEN MATTERS	LARGEST SETTLEMENT

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NOVEMBER 2026 · FULL REPORT

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IN THIS EDITION

87

CVS moves to first place after its $315 million federal opioid dispensing settlement and new state actions.

$315M

CVS's October settlement of the DOJ dispensing case, the largest new resolution of the period.

32

Open matters across the ten companies, with four new state actions logged since the last report.

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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 counts 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.

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

Weekly updates

Score changes are published weekly after editorial review, and all ten rankings are reviewed monthly.

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02

Methodology

Scores are a weighted composite of four factors applied to publicly verified enforcement records.

2.1

Regulatory action volume · 40%

The number of documented government enforcement matters, resolved and open, across federal and state jurisdictions in the review window.

2.2

Conduct severity · 30%

The gravity of the underlying conduct and the size of resolutions. Criminal resolutions and large dollar outcomes weigh more heavily than civil or non-monetary ones.

2.3

Institutional response quality · 20%

How a company responds: corporate integrity agreements and consent orders, appeals of adverse judgments, and subsidiary bankruptcies or other tactics that delay resolution.

2.4

Repeat enforcement exposure · 10%

Conduct substantially similar to that in an earlier resolution, particularly while the company operates under an existing agreement or order.

2.5

Weekly change rule

+1 for each new open government matter; +2 for a resolution of $100 million or more (doubled if criminal); +1 for a new compliance agreement, CIA or consent order; +1 for each matter in a conduct area where the company has resolved a government action before.

2.6

Temporal decay

Actions older than five years contribute at reduced weight. Actions over ten years old are shown for context only and do not count toward the score.

Update cadence. Score changes are published weekly after editorial review of newly logged matters, and all ten rankings are reviewed monthly regardless of new actions. Private class actions and product liability suits are excluded. Scores are not provided to covered companies before publication.

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03

Rankings · November 2026

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

#	COMPANY	SCORE	CASES	OPEN
1	**CVS Health Corporation** CVS	87	9	5
2	**Pfizer Inc.** PFE	85	8	5
3	**AbbVie Inc.** ABBV	70	6	3
4	**McKesson Corporation** MCK	67	3	1
5	**Johnson & Johnson** JNJ	62	4	3
6	**Eli Lilly and Company** LLY	59	8	5
7	**The Cigna Group** CI	59	6	5
8	**Bristol-Myers Squibb Company** BMY	57	4	2
9	**Amgen Inc.** AMGN	42	3	2
10	**Merck & Co., Inc.** MRK	36	3	1

AVERAGE SCORE	MEDIAN SCORE	CONTROVERSIES	OPEN MATTERS
62.4	60.5	54	32

Score changes this edition.

- **CVS** +6 · $315m DOJ dispensing settlement with DEA compliance agreement (repeat opioid conduct); Pennsylvania insulin suit; Oklahoma Caremark fees settlement
- **PFE** +1 · Florida AG suit over COVID-19 vaccine marketing
- **LLY** +4 · Pennsylvania insulin suit (repeat after 2024 Minnesota settlement); Missouri 340B cease-and-desist
- **CI** +2 · Arizona opioid suit; Pennsylvania insulin suit

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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.

87	**CVS Health Corporation** Rank 01 · CVS	07
85	**Pfizer Inc.** Rank 02 · PFE	08
70	**AbbVie Inc.** Rank 03 · ABBV	09
67	**McKesson Corporation** Rank 04 · MCK	10
62	**Johnson & Johnson** Rank 05 · JNJ	11
59	**Eli Lilly and Company** Rank 06 · LLY	12
59	**The Cigna Group** Rank 07 · CI	13
57	**Bristol-Myers Squibb Company** Rank 08 · BMY	14
42	**Amgen Inc.** Rank 09 · AMGN	15
36	**Merck & Co., Inc.** Rank 10 · MRK	16

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.

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RANK 01 · CVS · COMPANY PROFILE

CVS Health Corporation

87

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
87/100	9	5	$948.8M

WHY IT RANKS HERE

CVS moves to first place. It 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. In October it settled the federal opioid dispensing case for $315 million, a resolution in a conduct area where it has settled before.

THE RECORD

DOJ opioid dispensing settlement

On October 13, 2026 the DOJ announced that CVS Pharmacy and related entities would pay $315 million to resolve allegations that, from October 2013 to December 2025, its pharmacies filled excessive, early and dangerous opioid prescriptions, including from pill-mill prescribers. CVS also entered a memorandum of agreement with the DEA requiring a reporting hotline and proactive monitoring of dispensing. CVS admits no wrongdoing.

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 for drugs dispensed without valid prescriptions. In July 2025 the court entered judgment of $948.8 million, with CVS jointly liable for about $164.8 million. 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 plan was approved in September 2026.

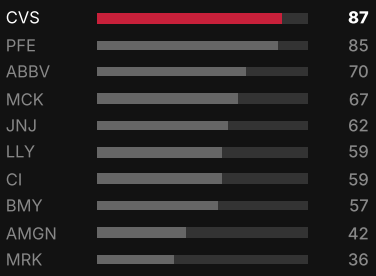
Caremark: Part D price reporting

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 pricing and PBM fees

Caremark is a defendant in Pennsylvania's October 9, 2026 insulin pricing suit. On October 30, 2026 Oklahoma announced it would distribute more than $2.1 million in fines from its third Caremark settlement over pharmacy transaction fees.

WHERE IT SITS



WHAT TO WATCH

- Implementation of the DEA agreement
- Third Circuit ruling on the Caremark judgment
- FTC decision on the Caremark order

CONTEXT

In October 2026 House Oversight asked Caremark for documents on pharmacy audits; the inquiry is not a finding.

SOURCES

DOJ (D.R.I.) release; E.D. Pa. and S.D.N.Y. judgments; FTC Docket 9437; state AG releases.

KEY MATTER	AMOUNT	DATE	STATUS
DOJ controlled-substances settlement + DEA agreement	$315M	Oct 13, 2026	**Resolved, no admission**
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.)
Pennsylvania AG insulin pricing suit	–	Oct 9, 2026	Active
FTC Caremark insulin rebate consent order	–	Jul 14, 2026	Pending finalisation

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RANK 02 · PFE · COMPANY PROFILE

Pfizer Inc.

85

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
85/100	8	5	$59.7M

WHY IT RANKS HERE

Pfizer now ranks second, one point behind CVS. Its largest resolved matter in the review window is under $60 million, but it carries open matters across federal and state jurisdictions, and Florida's October suit over COVID-19 vaccine marketing adds a third state case on the same conduct.

THE RECORD

Florida COVID-19 vaccine marketing suit

On October 1, 2026 Florida Attorney General James Uthmeier sued Pfizer and its chairman and chief executive, Albert Bourla, in St. Lucie County under the state's consumer-protection law, challenging statements about the vaccine's safety and effectiveness. The state seeks an injunction, disgorgement and civil penalties of up to $15,000 per violation. Pfizer says the claims lack merit. These are allegations; no court has made findings.

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 settlement resolved a whistleblower suit by a former Biohaven sales representative. 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. 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.

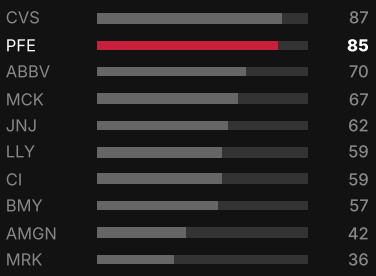
Texas COVID-19 vaccine marketing suit

Texas filed in November 2023 under the Deceptive Trade Practices Act, alleging Pfizer misrepresented its 95% efficacy figure. Judge Sam Cummings dismissed the case on PREP Act immunity grounds on December 30, 2024. Texas appealed to the Fifth Circuit in January 2025.

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

- Florida case in St. Lucie County
- 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; Florida AG complaint; D. Kan. remand order; Pfizer Form 10-Q.

KEY MATTER	AMOUNT	DATE	STATUS
Florida AG COVID-19 vaccine marketing suit	–	Oct 1, 2026	Active
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

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RANK 03 · ABBV · COMPANY PROFILE

AbbVie Inc.

70

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
70/100	6	3	$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. On March 17, 2026 the Ninth Circuit reversed a dismissal, holding that the False Claims Act provides an independent route to such claims. The court refused rehearing en banc on May 28, 2026, and the case returns to the district court.

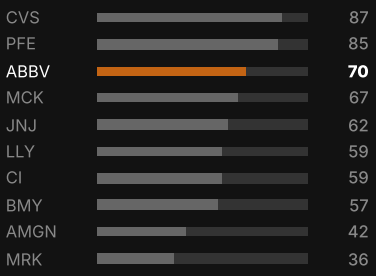
Humira marketing in California

In August 2020 AbbVie paid $24 million to California and a whistleblower to settle an insurance-fraud suit alleging it gave physicians free professional services to induce Humira prescriptions. AbbVie denied the allegations.

Promotional letters

FDA issued an untitled letter on Ubrelvy promotion in August 2024. AbbVie was also among the companies receiving 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

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**

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RANK 04 · MCK · COMPANY PROFILE

McKesson Corporation

67

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

WHY IT RANKS HERE

McKesson has few documented matters, but one is the largest single obligation in the index and the others 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 while supplying rising volumes of oxycodone and hydrocodone. The settlement suspended controlled-substance sales from centres in four states and imposed five years of enhanced compliance under an independent monitor.

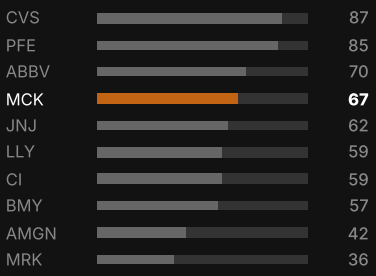
2022: the national distributor settlement

McKesson, Cardinal Health and AmerisourceBergen committed to resolve opioid claims by states and local governments, paid over 18 years. 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 repeat exposure 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 · repeat factor**
DEA suspicious-order settlement	$13.25M	2008	**Resolved · repeat factor**

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RANK 05 · JNJ · COMPANY PROFILE

Johnson & Johnson

62

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
62/100	4	3	$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 biggest items are either under appeal or resolved marketing claims, but either could move its score 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. A jury found Janssen liable in June 2024 on the off-label claims. On March 28, 2025 Judge Zahid Quraishi entered judgment of $1.64 billion. The Third Circuit heard Janssen's appeal in March 2026. 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. On March 31, 2025 Judge Christopher Lopez of the Southern District of Texas dismissed the case. J&J said it would return to defending claims in the tort system.

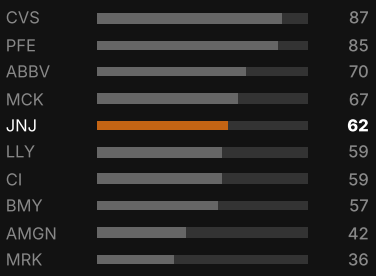
Talc marketing settlement

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 powders. 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 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**

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RANK 06 · LLY · COMPANY PROFILE

Eli Lilly and Company

59

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
59/100	8	5	$183.7M

WHY IT RANKS HERE

Lilly rose two places this edition. Pennsylvania named it in a new insulin pricing suit, its fifth state insulin case after the 2024 Minnesota settlement, and Missouri ordered it to drop a 340B claims-data condition. The Supreme Court's refusal to hear the Streck appeal in May 2026 had already made a long-running dispute a final adverse judgment.

THE RECORD

Missouri 340B cease-and-desist

On October 26, 2026 Missouri Attorney General Catherine Hanaway ordered Lilly to stop conditioning 340B discounts for Missouri hospitals on the submission of claims data, alleging a breach of the Missouri Merchandising Practices Act. Lilly had cut University of Missouri Health Care off from 340B pricing in July. The letter set a November 26 deadline.

Insulin pricing

Lilly is a defendant in Pennsylvania's October 9, 2026 suit against the three largest insulin makers and PBMs, alongside cases brought by Texas, Oregon and Missouri. In February 2024 it settled with Minnesota, agreeing to cap insulin at $35 a month for eligible residents, with no monetary penalty and no admission.

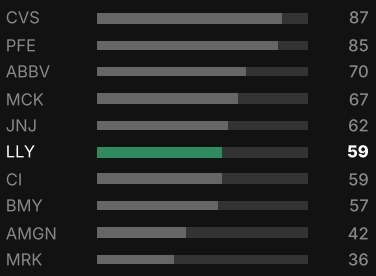
Medicaid rebate judgment

A whistleblower sued in 2014 alleging Lilly concealed retroactive price increases and underpaid Medicaid rebates. A jury found Lilly liable in August 2022; the award was trebled to $183.7 million. The Seventh Circuit affirmed in September 2025 and the Supreme Court denied certiorari on May 18, 2026. With interest the judgment exceeds $220 million.

Texas kickback suit and FDA letters

In August 2025 Texas sued alleging Lilly offered providers free nurses and reimbursement support to induce prescriptions of Mounjaro, Zepbound and other drugs. On September 9, 2025 FDA issued Lilly three warning letters over tirzepatide promotion.

WHERE IT SITS



WHAT TO WATCH

- Lilly's response to the Missouri deadline
- Pennsylvania, Texas and Oregon insulin cases
- Proceedings in the Texas kickback suit

CONTEXT

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

SOURCES

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

KEY MATTER	AMOUNT	DATE	STATUS
Missouri AG 340B cease-and-desist	–	Oct 26, 2026	Open
Pennsylvania AG insulin pricing suit	–	Oct 9, 2026	Active
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
Minnesota insulin pricing settlement	No monetary penalty	Feb 7, 2024	Resolved

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RANK 07 · CI · COMPANY PROFILE

The Cigna Group

59

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
59/100	6	5	$172.3M

WHY IT RANKS HERE

Cigna has the fastest-growing docket in the index. Its Express Scripts unit picked up two more state actions in October, Arizona's opioid suit and Pennsylvania's insulin case, on top of the Michigan, Florida and Louisiana antitrust suits filed since April 2025.

THE RECORD

Arizona opioid suit

On October 1, 2026 Arizona Attorney General Kris Mayes sued Express Scripts and Optum under the Arizona Consumer Fraud Act, alleging that confidential rebate deals gave OxyContin preferred formulary status without prior-authorisation controls. The case is at the pleading stage.

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. Cigna entered a five-year corporate integrity agreement.

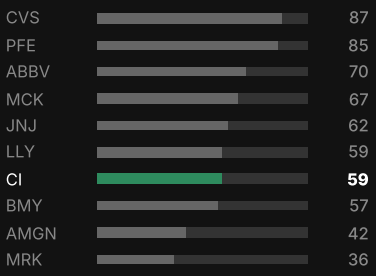
FTC insulin rebate order

On February 4, 2026 the FTC settled its case against Express Scripts. The terms delink PBM pay from list prices and require net-cost formulary options. The order carries no monetary penalty and the respondents denied the charges.

State antitrust and pricing suits

Michigan sued Express Scripts and Prime Therapeutics in April 2025; Florida filed on similar grounds on August 27, 2026, and Louisiana sued Express Scripts and Ascent on August 31, 2026. Express Scripts is also a defendant in the Pennsylvania insulin suit filed on October 9, 2026, and in the Texas and Oregon insulin cases. On September 18, 2026 the Sixth Circuit kept Kentucky's opioid suit against Express Scripts in federal court.

WHERE IT SITS



WHAT TO WATCH

- Arizona and Kentucky opioid cases
- Michigan, Florida and Louisiana antitrust cases
- House Oversight inquiry into PBM audits
- Compliance under the FTC order and the CIA

CONTEXT

In October 2026 House Oversight asked Express Scripts for documents on pharmacy audits; the inquiry is not a finding.

SOURCES

DOJ (E.D. Pa.) release; FTC release; Arizona, Pennsylvania, Michigan, Florida and Louisiana AG filings; Sixth Circuit docket.

KEY MATTER	AMOUNT	DATE	STATUS
Arizona AG opioid suit (ESI / Optum)	–	Oct 1, 2026	Active
Pennsylvania AG insulin pricing suit	–	Oct 9, 2026	Active
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, Louisiana antitrust suits	–	Apr 2025 – Aug 2026	Active

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RANK 08 · BMY · COMPANY PROFILE

Bristol-Myers Squibb Company

57

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
57/100	4	2	$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 Plavix works less well in patients with a common genetic variation. After a bench trial the court awarded $834 million, raised to about $916 million on retrial in May 2024. The companies 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 Otezla, which went to Amgen for $13.4 billion, and imposes continuing obligations.

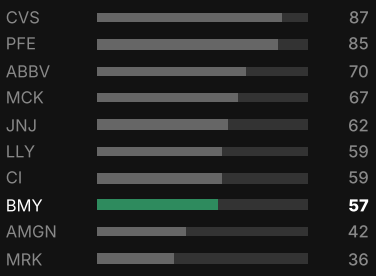
Medicare price negotiation

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.

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**

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RANK 09 · AMGN · COMPANY PROFILE

Amgen Inc.

42

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
42/100	3	2	$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. The case settled, and the final order entered on December 13, 2023 bars bundling and rebate conditions involving Tepezza and Krystexxa, requires prior approval for certain acquisitions, and runs for 15 years under an FTC-appointed monitor. Amgen denied the alleged violations.

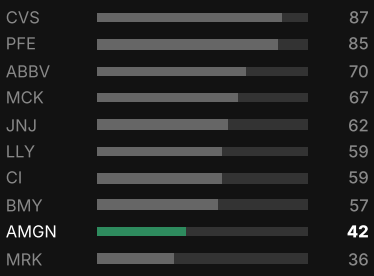
Copay charities

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. The matter now carries reduced weight.

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**

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RANK 10 · MRK · COMPANY PROFILE

Merck & Co., Inc.

36

SCORE	CONTROVERSIES	OPEN MATTERS	LARGEST ITEM
36/100	3	1	$16.7M

WHY IT RANKS HERE

Merck ranks last. It has 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. 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.

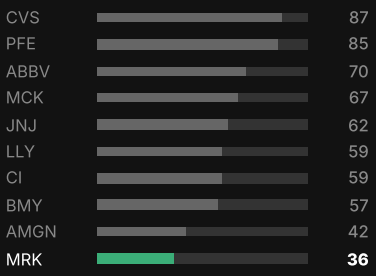
Animal Health promotion

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.

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**

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Key findings

Seven themes from the November 2026 edition.

01 **CVS takes first place**

CVS's $315 million settlement of the federal opioid dispensing case on October 13, with a DEA agreement attached, is the largest new resolution of the period and its second resolved opioid matter. With the Pennsylvania insulin suit and a third Oklahoma fee settlement, it moves ahead of Pfizer.

02 **State attorneys general are driving the docket**

Every new open matter logged this period came from a state: Florida against Pfizer, Arizona against Express Scripts and Optum, Pennsylvania against the insulin makers and PBMs, and Missouri against Lilly. Federal activity was concentrated in resolutions rather than new suits.

03 **Insulin pricing is now a five-state front**

Pennsylvania's October 9 suit joins Texas, Oregon, Missouri and earlier Minnesota action against Lilly and the three largest PBMs. Pennsylvania's case runs on deception claims because it has no general antitrust statute.

04 **PBMs face scrutiny from every direction**

Caremark and Express Scripts carry FTC consent terms, state antitrust and opioid suits, and from October 23 a House Oversight inquiry into whether PBMs used audits against pharmacies that backed reform. The inquiry is not a finding but adds political pressure.

05 **340B becomes a state enforcement issue**

Missouri's cease-and-desist to Lilly uses consumer-protection law to challenge manufacturer conditions on 340B discounts, alongside the Ninth Circuit's March ruling opening False Claims Act suits against manufacturers such as AbbVie.

06 **Self-disclosure gets cheaper**

The DOJ and HHS opened a six-month False Claims Act self-disclosure pilot on October 22, with repayment multipliers of 1.25 to 1.6 times and no corporate integrity agreement. Any disclosures by indexed companies would surface as resolved matters in later editions.

07 **Opioid obligations persist**

McKesson, AbbVie's Allergan, J&J and CVS all carry active multi-year opioid settlement obligations. CVS's October settlement shows that federal dispensing claims continue alongside the 2022 state settlements.

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RegulationWatch

Selected enforcement reporting involving indexed companies, most recent first.

Oct 30, 2026	STATE ENFORCEMENT	Oklahoma to pay out $2.1M from third CVS Caremark fee settlement	CVS
Oct 26, 2026	340B PROGRAM	Missouri orders Eli Lilly to drop 340B claims-data condition	LLY
Oct 23, 2026	PBM OVERSIGHT	House Oversight chair investigates PBM audits of pharmacies	CVS · CI
Oct 22, 2026	FALSE CLAIMS ACT	DOJ and HHS open FCA self-disclosure window	All
Oct 13, 2026	CONTROLLED SUBSTANCES	CVS agrees to pay $315M to settle federal opioid dispensing case	CVS
Oct 9, 2026	DRUG PRICING	Pennsylvania sues insulin makers and PBMs over pricing	LLY · CI · CVS
Oct 1, 2026	OPIOID LITIGATION	Arizona sues Express Scripts and Optum over opioid rebate deals	CI
Oct 1, 2026	STATE ENFORCEMENT	Florida sues Pfizer and Albert Bourla over vaccine marketing	PFE
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

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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. Manufacturer conditions on discounts have generated active litigation and state enforcement.

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.

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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 November 2026.

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