AIMEDALLIANCE

Litigation & Case Law TRACKER

November 2, 2026

Aimed Alliance's *Litigation & Case Law Tracker* summarizes developments in legal cases and the law that could affect the rights of U.S. health care consumers and providers. This quarterly publication also highlights the judicial-branch advocacy efforts of Aimed Alliance and its not-for-profit allies.

This issue of our *Litigation & Case Law Tracker* covers the period from July 14, 2026, through October 30, 2026.

We welcome feedback at policy@aimedalliance.org.

Judicial Branch Advocacy

Former FDA Commissioners File Amicus Brief Defending Mifepristone REMS

July 21 – A group of former and acting U.S. Food and Drug Administration (FDA) commissioners filed an amicus brief in a lawsuit filed by the state of Louisiana challenging FDA's changes to its Risk Evaluation and Mitigation Strategy (REMS) for mifepristone. The brief asserts that the FDA's approval of mifepristone and subsequent REMS modifications were based on decades of scientific review, clinical studies, and postmarket safety data. It contends that the agency's 2021 and 2023 decisions to remove the in-person dispensing requirement were supported by extensive evidence showing no significant safety concerns and warned that rejecting the FDA's reliance on adverse-event reporting data would undermine the agency's longstanding, science-based drug regulatory system. The filing was one of more than 20 amicus briefs filed in support of the FDA, reflecting broad backing from former officials, medical groups, states, lawmakers, and advocacy organizations.

The case is State of Louisiana v. Food and Drug Administration, number 26-30203, in the U.S. Court of Appeals for the Fifth Circuit.

A previous summary of this case can be found in the July 2026 edition of our Litigation & Case Law Tracker.

Federal Policy

Broker Group Challenges CMS Moratorium on New ACA Marketplace Registrations

October 15 – A trade association representing health insurance brokers and agents sued the Centers for Medicare & Medicaid Services (CMS), challenging both a September interim final rule that authorized CMS to temporarily suspend new agent and broker registrations and a subsequent moratorium that bars new registrations for the 2027 Affordable Care Act (ACA) marketplace plan year.

The National Association of Benefits and Insurance Professionals argues that the U.S. Department of Health and Human Services (HHS} violated the Administrative Procedure Act (APA) by issuing an interim final rule without first conducting notice-and-comment rulemaking. The rule gave CMS authority to suspend new registrations when broker conduct poses an "unacceptable risk" to the operation of federally facilitated exchanges. HHS, however, maintains that it had "good cause" to bypass the normal rulemaking process because providing advance notice would have been contrary to the public interest and could have undermined efforts to address marketplace fraud and abuse.

The case is National Association of Benefits and Insurance Professionals v. Kennedy et al., number 1:26-cv-04311-SAG, in the U.S. District Court for the District of Maryland.

PhRMA Challenges CMS GLOBE Medicare Drug Pricing Model

October 7 – Pharmaceutical Research and Manufacturers of America (PhRMA) sued CMS to challenge the implementation of the agency's new Medicare Part B payment model, the Global Benchmark for Efficient Drug Pricing (GLOBE). The rule would require manufacturers of certain high-cost Part B drugs to pay rebates when U.S. prices exceed a benchmark derived from prices in 19 foreign countries.

The model is scheduled to launch as a five-year demonstration beginning in April and would apply to roughly 25 percent of Medicare Part B fee-for-service beneficiaries selected by ZIP code. Manufacturers that fail to pay the required rebates would face financial penalties.

According to the complaint, Section 1115A of the Social Security Act permits CMS to test payment and service delivery models, not to impose a foreign-reference pricing regime through mandatory rebates. PhRMA argues that GLOBE exceeds the agency's limited demonstration authority by effectively imposing drug price controls that Congress has declined to authorize. PhRMA further argues that the rule represents a major policy change with significant economic consequences and therefore violates the major questions doctrine. The group asks the court to invalidate the rule before it takes effect.

The case is Pharmaceutical Research and Manufacturers of America v. Kennedy et al., number 1:26-cv-03498, in the U.S. District Court for the District of Columbia.

California Judge Allows States' Vaccine Recommendation Challenge to Proceed

September 8 – After a coalition of states sued HHS over its decision to remove several childhood vaccine recommendations and overhaul the Centers for Disease Control and Prevention's (CDC) vaccine advisory committee, a California federal judge largely denied the government's motion to dismiss and allowed the case to proceed. The court found the states sufficiently alleged that the changes could increase health care costs by requiring them to respond to outbreaks of vaccine-preventable diseases associated with lower vaccination rates and could require revisions to state laws and health care programs, though some

claims were dismissed. The lawsuit contends that HHS violated the APA by revising the childhood immunization schedule, replacing members of the Advisory Committee on Immunization Practices (ACIP), and changing recommendations for the hepatitis B vaccine.

The case is State of Arizona et al. v. Kennedy et al., number 3:26-cv-01609, in the U.S. District Court for the Northern District of California.

States Challenge 2026 ACA Rule Reimposing Previously Vacated Provisions

July 31 – A coalition of 21 states sued HHS and CMS to challenge a 2026 ACA rule the plaintiffs allege unlawfully reinstates four provisions previously vacated by a Maryland federal court and imposes new requirements that undermine the ACA's single risk pool, including by expanding eligibility for catastrophic health plans beyond statutory limits and increasing maximum out-of-pocket cost-sharing limits for catastrophic and bronze-tier plans above statutory caps. According to the complaint, these changes will lead to lower enrollment, increased compliance burdens for state-run exchanges, and greater expenses for states as more residents become uninsured. The states seek to vacate the challenged provisions under the APA and block their implementation.

The case is State of California et al. v. Kennedy et al., number 4:26-cv-07991, in the U.S. District Court for the Northern District of California.

Maryland Judge Stays Key ACA Marketplace Rule Provisions

July 16 – A Maryland federal judge stayed portions of a May 2026 ACA marketplace rule scheduled to take effect on July 20, finding that a coalition of physician, small-business, and local-government plaintiffs was likely to succeed on claims that several provisions violate the APA. The challenged rule revises eligibility and verification requirements for premium subsidies and special enrollment periods, updates certain coverage standards, and eliminates standardized health plans. The plaintiffs argued that multiple provisions were contrary to law or arbitrary and capricious and sought to delay their implementation. The court concluded that the plaintiffs were likely to succeed on the merits of certain challenges, would suffer irreparable harm absent relief, and that the balance of equities and public interest favored a stay.

The case is City of Columbus et al. v. Kennedy et al., number 1:26-cv-02215, in the U.S. District Court for the District of Maryland.

A previous summary of this case can be found in the July 2026 edition of our *Litigation & Case Law Tracker.*

Judge Keeps States' Challenge to Trump Public Health Funding Cuts in Federal Court

July 21 – An Illinois federal judge denied the Trump administration's request to transfer a lawsuit over public health funding cuts to the U.S. Court of Federal Claims, ruling that the federal district court has jurisdiction. The suit, brought by Illinois, California, Colorado, and Minnesota, challenges the termination of more than $600 million in Centers for Disease Control and Prevention public health grants, alleging

the cuts unlawfully targeted Democratic-led states for political reasons. The court held that the case is a challenge to federal agency action and the administration of grant programs, rather than a contract dispute seeking money damages under the Tucker Act.

The case is State of Illinois et al. v. Vought et al., number 1:26-cv-01566[DM1.1], in the U.S. District Court for the Northern District of Illinois.

A previous summary of this case can be found in the April 2026 edition of our *Litigation & Case Law Tracker*.

Aimed Alliance is monitoring several other cases relating to federal policy, including those listed below. We will report any dispositive developments in these matters in future editions of our *Litigation & Case Law Tracker*.

- **American Academy of Pediatrics et al. v. Kennedy et al.**, number 1:25-cv-11916, in the U.S. District Court for the District of Massachusetts.
- **American Association Of Nurse Practitioners et al. v. McMahon et al.**, number 1:26-cv-01780, in the U.S. District Court for the District of Columbia.
- **State of New York et al. v. Robert F. Kennedy Jr. et al.**, number 1:25-cv-00196, in the U.S. District Court for the District of Rhode Island.

Alternative Funding Providers

Fourth Circuit Upholds Injunction Against Importation of Prescription Drugs

August 13 – The Fourth Circuit upheld a preliminary injunction barring several defendants, including alternative funding program vendor Rx Valet, from importing and distributing foreign-market versions of Gilead's HIV medication Biktarvy in the United States. The court found that the imported products were not "genuine" for trademark-law purposes because they contained materially different labeling, warnings, prescribing information, and regulatory disclosures from U.S.-approved versions.

The suit arose after a Maryland patient received a bottle of Biktarvy intended for sale in Turkey. Gilead alleges that Rx Valet, its affiliate Advanced Pharmacy, referral service Affordable Rx, and company executive Gregory Santulli participated in a scheme to obtain and distribute foreign-market drugs through employer-sponsored health plans. Gilead also alleges that Meritain Health, a CVS Health and Aetna subsidiary, and pharmacy-benefit administrator ProAct helped facilitate the arrangement through the health plans they serviced. The ruling leaves in place the lower court's order while the trademark case proceeds.

The case is Gilead Sciences, Inc. v. Meritain Health Inc., number 25-1828, in the U.S. Court of Appeals for the Fourth Circuit.

A previous summary of this case can be found in the July 2025 edition of our *Litigation & Case Law Tracker.*

Aimed Alliance is monitoring the following additional cases relating to alternative funding providers. We will report any dispositive developments in these matters in future editions of our *Litigation & Case Law Tracker*.

- **AbbVie Inc. v. Payer Matrix LLC**, number 1:23-cv-02836, in the U.S. District Court for the Northern District of Illinois.
- **Gurwitch v. Save On SP LLC**, number 1:25-cv-00006 in the U.S. District Court for the Western District of New York.
- **Sharx, LLC v. AbbVie Inc.**, number 2024-L-000264 in the Circuit Court of Cook County, Illinois.

Cannabinoids

DEA Administrative Judge Keeps Marijuana Rescheduling Record Closed After GAO Report

October 22 – A chief administrative law judge (ALJ) admitted a recent Government Accountability Office (GAO) report into the record of the federal marijuana rescheduling proceeding but denied opponents' request to reopen the hearing for additional discovery and testimony. Instead, the ALJ directed the parties to address the report through supplemental briefing.

The dispute concerns the DEA's proposal to move marijuana from Schedule I to Schedule III under the Controlled Substances Act. Opponents argued the GAO report raised questions about aspects of the agencies' review process and warranted further fact-finding. The ALJ, however, concluded that the existing record was sufficient, stating that the report speaks for itself and that any alleged shortcomings in the government's evidence should be weighed on the merits rather than used to justify reopening the proceedings.

The case is In the Matter of Schedules of Controlled Substances: Proposed Rescheduling of Marijuana, DEA Docket No. 1362, Hearing Docket No. 26-96, in the U.S. Department of Justice, Drug Enforcement Administration.

A previous summary of this case can be found in the July 2026 edition of our *Litigation & Case Law Tracker.*

Aimed Alliance is monitoring the following additional cases relating to cannabinoids. We will report any dispositive developments in these matters in future editions of our *Litigation & Case Law Tracker*.

- **Michael Murray et al. v. Cresco Labs Inc. et al.**, number 3:26-cv-50184, in the U.S. District Court for the Northern District of Illinois.
- **Rossow et al. v. Charron**, number 1:23-cv-00131-BLW, in the U.S. District Court for the District of Idaho.

Compounding

Court Upholds Dismissal of Compounding Pharmacy's GLP-1 Antitrust Challenge

October 20 – A Texas federal judge denied Strive Specialties Inc.'s request to reconsider the dismissal of its antitrust lawsuit against Eli Lilly & Co. and Novo Nordisk A/S. The compounding pharmacy had alleged that the drugmakers unlawfully restricted competition in the market for GLP-1 medications and that Eli Lilly used exclusive agreements with telehealth providers to exclude compounding pharmacies.

The court found that Strive's motion was based on a misunderstanding of the law and upheld its earlier decision dismissing the case with prejudice. The judge reiterated that Strive failed to plausibly allege violations of the Sherman or Clayton Acts because its compounded GLP-1 products were not meaningful market substitutes for the branded GLP-1 drugs sold by Eli Lilly and Novo Nordisk.

The case is Strive Specialties Inc. v. Eli Lilly & Co. et al., number 5:26-cv-00155, in the U.S. District Court for the Western District of Texas.

Eli Lilly Sues Sellers Over Marketing of Unapproved Retatrutide Products

October 10 – Eli Lilly and Co. filed lawsuits against an Arizona weight-loss clinic and three online sellers, alleging they are unlawfully marketing and selling products containing retatrutide, Lilly's investigational weight-loss molecule, which remains in clinical trials and has not been approved by the U.S. Food and Drug Administration (FDA).

According to the complaints, the defendants promote retatrutide as a weight-loss treatment and, in some cases, claim it is more effective than Lilly's approved medicines, Mounjaro and Zepbound, despite retatrutide still being an investigational drug molecule undergoing clinical testing. Lilly contends that the sales pose risks to consumers, divert demand from its approved products, and improperly capitalize on the company's investment in research, development, and regulatory review while avoiding the associated costs, oversight, and patient-safety obligations.

Lilly further alleges that the defendants' false and misleading promotion of unauthorized retatrutide products violates the Lanham Act. The company seeks a permanent injunction prohibiting the marketing, sale, and distribution of products containing or purporting to contain retatrutide, as well as corrective advertising, disgorgement of profits, damages, attorneys' fees, and costs.

The lawsuits follow a series of related actions filed in August by Lilly against a California medical spa, a Texas compounding pharmacy, and several chemical suppliers accused of illegally marketing and selling retatrutide. Those cases allege that Aesthetic Envy promoted retatrutide's weight-loss benefits to

consumers, Striker Pharmacy supplied retatrutide to consumers and medical practices, and Astra Peptides, Legendary Peptides, Texas Peptides, and Lone Star Peptides marketed retatrutide as a product for "research use only" while allegedly selling it for human use. Lilly notes that the FDA has issued 16 warning letters to companies marketing retatrutide products.

The cases are Eli Lilly and Co. v. MedShape Weight Loss Clinic LLC, number 2:26-cv-07361, in the U.S. District Court for the District of Arizona; Eli Lilly and Co. v. Brown d/b/a LiveWell Peptides, number 3:26-cv-03514, in the U.S. District Court for the Northern District of Texas; Eli Lilly and Co. v. Cenexa Labs LLC, number 4:26-cv-08806, in the U.S. District Court for the Southern District of Texas; and Eli Lilly and Co. v. American Peptides LLC, number 5:26-cv-04146, in the U.S. District Court for the Western District of Louisiana.

The earlier cases are Eli Lilly and Co. v. Aesthetic Envy Centers LLC, number 2:26-at-01347, in the U.S. District Court for the Eastern District of California; Eli Lilly and Co. v. Astra LLC, number 5:26-cv-05147, in the U.S. District Court for the Western District of Texas; Eli Lilly and Co. v. Texas Peptides Inc., number 5:26-cv-05146, in the U.S. District Court for the Western District of Texas; Eli Lilly and Co. v. Legendary Peptides LLC, number 1:26-cv-00347, in the U.S. District Court for the Eastern District of Texas; Eli Lilly and Co. v. Lone Star Peptide Co. LLC, number 4:26-cv-06562, in the U.S. District Court for the Southern District of Texas; Eli Lilly and Co. v. Striker Pharmacy LLC, number 4:26-cv-06563, in the U.S. District Court for the Southern District of Texas.

California Judge Partially Preserves Core of Eli Lilly's Compound Tirzepatide Suit

September 8 – A California federal judge issued a mixed ruling in Eli Lilly's lawsuit accusing Mochi Health, affiliated physician groups, and Aequita Pharmacy of working together to market and dispense compounded tirzepatide.

The court allowed Lilly to proceed with its claim that Aequita Pharmacy and its corporate parent participated in a conspiracy to violate California's unfair competition law through the alleged corporate practice of medicine, finding Lilly had plausibly alleged knowledge of and participation in the scheme.

However, the judge dismissed Lilly's conspiracy claims based on alleged Lanham Act violations, concluding that Lilly had not adequately alleged that the Mochi Medical or Aequita defendants took actions to further Mochi Health's allegedly false advertising. The court found further amendment would be futile, though Lilly may seek to revive the theory if it uncovers new supporting facts.

The ruling leaves intact Lilly's Lanham Act and unfair competition claims against Mochi Health.

The case is Eli Lilly and Co. v. Mochi Health Corp. et al., number 3:25-cv-03534, in the U.S. District Court for the Northern District of California.

A previous summary of this case can be found in the July 2026 version of our *Litigation & Case Law Tracker.*

Fifth Circuit Affirms FDA Shortage Determinations for Lilly and Novo Nordisk GLP-1 Drugs

August 27 – A three-judge panel upheld a Texas federal court's decisions declining to overturn the FDA's removal of Mounjaro, Zepbound, Ozempic, and Wegovy from the federal drug shortage list, a move that ended compounding pharmacies' ability to produce copies of those medicines. The plaintiffs, Outsourcing Facilities Association and FarmaKeio Custom Compounding, argued that the agency violated the APA by removing the drugs from the shortage list without notice-and-comment rulemaking and that the shortage determinations were arbitrary and capricious.

The panel did not decide whether the FDA's underlying shortage determinations were correct. Instead, it held that any procedural shortcomings were harmless because the compounding facilities had "actual" notice of the FDA's decisions, an opportunity to provide comments, and advance notice before the removals took effect. The court also found that the FDA adequately disclosed the data periods it analyzed and reasonably relied on supply-and-demand information provided by Eli Lilly and Novo Nordisk. Finally, the panel rejected the plaintiffs' contention that the manufacturers' data still showed shortages, finding their analysis of the data was flawed because it failed to account for surplus inventory carrying over between months.

The case is Outsourcing Facilities Association et al. v. Food & Drug Administration et al., number 25-10600, in the U.S. Court of Appeals for the Fifth Circuit.

The district court case is Outsourcing Facilities Association et al. v. FDA et al., number 4:24-cv-00953, in the U.S. District Court for the Northern District of Texas.

A previous summary of the lower court case can be found in the July 2025 issue of our *Litigation & Case Law Tracker.*

Texas Judge Lets Lilly's Tirzepatide Claims Against Revive Rx Move Forward

August 4 – A Texas federal judge denied Revive Rx's motion to dismiss Eli Lilly's remaining unfair-competition claims, allowing the drugmaker's claims under the laws of seven states to proceed. The court rejected Revive's argument that compounded drugs are categorically exempt from state and federal "new drug" requirements, holding that compounded products can qualify as new drugs depending on their composition and use.

The dispute stems from Eli Lilly's allegations that Revive Rx unlawfully mass-produced and distributed compounded tirzepatide products, the active ingredient in Mounjaro and Zepbound, without complying with applicable pharmacy and drug-approval requirements. Lilly contends that Revive's products compete with its FDA-approved medicines while avoiding the costs and regulatory obligations of the approval process.

Judge Lee Rosenthal emphasized that the ruling does not determine whether Revive ultimately violated state pharmacy or drug laws. Instead, whether Revive obtained required patient-specific prescriptions and engaged in lawful compounding rather than unlawful manufacturing, will be addressed later in the litigation. The case is one of 10 lawsuits Lilly filed in September 2023 against compounding pharmacies and related businesses over compounded tirzepatide products.

The case is Eli Lilly and Company v. Revive Rx LLC, number 4:23-cv-03521, in the U.S. District Court for the Southern District of Texas.

Novo Nordisk Granted Leave to Amend After Zealthy False Advertising Suit Dismissed

October 28 – In August, a New York federal judge dismissed Novo Nordisk's false advertising lawsuit against Zealthy, a telehealth company that connects patients with providers who prescribe weight-loss medications, finding that the drugmaker failed to adequately allege that Zealthy falsely represented compounded semaglutide products as FDA-approved or equivalent to Novo Nordisk's branded drugs, Wegovy and Ozempic. The court granted Zealthy's motion to dismiss but allowed Novo Nordisk 30 days to amend its complaint, noting that adequately pleaded allegations could support standing and a presumption of competitive injury. Novo Nordisk subsequently filed an amended complaint on September 1, and Zealthy moved to dismiss the revised claims on October 28. The ruling comes as Zealthy separately faces a lawsuit by the federal government alleging it misled consumers about the costs of medications obtained through its platform.

The case is Novo Nordisk A/S et al. v. Zealthy Inc., number 1:25-cv-06391, in the U.S. District Court for the Southern District of New York.

Aimed Alliance is monitoring the following additional cases relating to drug compounding. We will report any dispositive developments in these matters in future editions of our *Litigation & Case Law Tracker*.

- **Donoho et al. v. Hims & Hers Health Inc. et al.**, number 1:26-cv-01954, in the U.S. District Court for the Northern District of Illinois.
- **Eli Lilly and Co. v. North American Custom Laboratories LLC**, number 3:25-cv-02876, in the U.S. District Court for the Northern District of Texas.
- **In Re Hims & Hers Health, Inc. Securities Litigation**, number 3:25-cv-05315 in the U.S. District Court for the Northern District of California.
- **Novo Nordisk A/S, et al. v. Mochi Health Corp., et al**., number 5:25-cv-06563, in the U.S. District Court for the Northern District of California.

Drug Price Caps

Distributor Trade Group Loses Appeal to Preliminarily Block CT Price Cap Law

October 20 – A Second Circuit panel affirmed an order by the U.S. District Court for the District of Connecticut that denied Healthcare Distribution Alliance's motion for preliminary injunction in the trade group's bid to block the Connecticut Drug Price Cap (Public Act No. 25-168). The law establishes a price cap for brand-name drug or biological products to which all exclusive marketing rights have expired for at least twenty-four months, generic drugs, and interchangeable biological products sold in the state. The

Second Circuit held that the lower court did not abuse its discretion in rejecting the plaintiff's arguments that the law violates the U.S. Constitution's dormant commerce clause by discriminating against out-of-state entities and reaching beyond Connecticut's borders.

The case is Healthcare Distribution Alliance v. Boughton et al., number 25-3216, in the U.S. Court of Appeals for the Second Circuit.

Fifth Circuit Rejects Trade Groups' Challenge to Drug Price Negotiation Program

August 26 – The Fifth Circuit affirmed the Western District of Texas' decision to grant summary judgment to HHS, ending a constitutional challenge to the Inflation Reduction Act's (IRA) Drug Price Negotiation Program by PhRMA and two other trade groups. The plaintiffs alleged that the program violated the non-delegation doctrine, the Eighth Amendment's Excessive Fines clause, and the Fifth Amendment's Due Process Clause. The court disagreed, holding that the IRA complies with the nondelegation doctrine because it contains an intelligible principle to guide HHS, and does not implicate the Fifth Amendment because the plaintiffs lack a protected interest in selling at their preferred prices given that their participation in Medicare and Medicaid is voluntary. It also held that the excise tax used to enforce IRA compliance does not violate the Excessive Fines Clause because courts have never applied the prohibition outside of the criminal or quasi-criminal context.

The case is National Infusion Center Association et al. v. Kennedy et al., number 25-50661, in the U.S. Court of Appeals for the Fifth Circuit.

A previous summary of this case can be found in the October 2025 issue of our *Litigation & Case Law Tracker.*

Merck Loses Challenge to Drug Price Negotiation Program

August 24 – The U.S. District Court for the District of Columbia granted HHS's motion for summary judgment in Merck's constitutional challenge to the Drug Price Negotiation Program. In granting the government's motion, the court held that the program neither amounts to an unconstitutional taking under the Fifth Amendment, nor compels speech in violation of the First Amendment, because the drugmaker's participation in the program is voluntary.

The case is Merck & Co., Inc. v. Becerra et al., number 1:23-cv-01615, in the U.S. District Court for the District of Columbia.

Aimed Alliance is monitoring the following additional case relating to drug price caps. We will report any dispositive developments in this matter in future editions of our *Litigation & Case Law Tracker*.

- **Amgen Inc. et al. v. Gail Mizner et al.**, number 1:25-cv-03452, in the U.S. District Court for the District of Colorado.

False Claims Act

DOJ Charges 15 in Alleged Largest-Ever Addiction Treatment Fraud Scheme

October 21 – The U.S. Department of Justice (DOJ) announced criminal charges against 15 individuals in several alleged health care fraud schemes in the Los Angeles area, including what prosecutors described as the largest substance abuse treatment fraud case ever brought by the federal government. According to the Department, the schemes generated roughly $2 billion in fraudulent claims, including $1.6 billion tied to a yearslong operation that allegedly recruited vulnerable individuals into sham addiction treatment programs.

Prosecutors allege that defendants Nathan Young, David Young, Honey Phipps, and Cody Phipps operated a network of substance abuse treatment facilities and used "body brokers" to recruit unhoused and low-income individuals, often targeting people with generous insurance coverage or fraudulently enrolling them in plans offering higher reimbursements. The indictment alleges that patients were lured with free travel, housing, cash, gift cards, marijuana, cigarettes, and other incentives.

Once enrolled, patients were allegedly subjected to unnecessary or fraudulent detoxification and treatment services designed to maximize insurance billing. Prosecutors claim the defendants coached patients to exaggerate symptoms, supplied drugs to keep them in treatment, and in some instances used sedation or other tactics to prevent them from leaving facilities. The purported treatment often consisted of large virtual group sessions with little or no meaningful participation, while insurers were billed as if comprehensive addiction services had been provided. The defendants face charges including health care fraud, wire fraud conspiracy, money laundering, and illegal patient-referral payments.

The cases are *U.S. v. Nathan Young et al.*, number 2:26-cr-00670; *U.S. v. Richard Keech*, number 2:26-cr-00652; *U.S. v. Armani Raffi*, number 2:26-cr-00663; *U.S. v. Thomas Steven Mladinich*, number 8:26-cr-00121; and *U.S. v. Christina Mareik*, number 2:26-mj-03520, in the U.S. District Court for the Central District of California.

340B Drug Pricing

Hospitals Challenge Revised 340B Drug Rebate Program, Citing Financial Burdens and Prior Court Rulings

October 9 – The American Hospital Association and four safety-net hospitals sued HHS, seeking to block a revised 340B rebate program that would replace upfront drug discounts with an after-the-fact rebate process. Under the policy, hospitals would have to pay the full cost of certain drugs and submit information to manufacturers to verify eligibility before receiving the 340B discount.

The plaintiffs argue the policy would impose substantial financial and administrative burdens on hospitals serving low-income patients and that regulators underestimated those costs while overstating the program's benefits. They also contend that the revised proposal suffers from the same flaws as an earlier rebate plan that was challenged in court and blocked after a federal court found the government had failed to adequately consider its impact on hospitals and other providers. According to the lawsuit,

the new rule remains largely unchanged and fails to consider alternative methods for verifying hospitals' eligibility for 340B discounts.

The case is the American Hospital Association et al. v. Robert F. Kennedy Jr. et al., number 1:26-cv-00515, in the U.S. District Court for the District of Maine.

Court Dismisses Trade Group's Challenge to Colorado 340B Drug Delivery Law

September 1 – The U.S. District Court for the District of Colorado dismissed PhRMA's challenge to a Colorado law that prohibits drug manufacturers from interfering with the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B covered entity or its contract pharmacy. The court found that the plaintiff failed to show that the law conflicts with the federal 340B program because the federal law does not address the delivery or distribution of 340B drugs to patients. Furthermore, the court found that the law does not regulate business activity outside of the state given that the law does not set prices and therefore does not control out-of-state transactions. The court dismissed all of the plaintiff's claims with prejudice, meaning that the plaintiff cannot file the same claims again.

The case is Pharmaceutical Research and Manufacturers of America v. Weiser et al., number 1:25-cv-02437, in the U.S. District Court for the District of Colorado.

Third Colorado Federal Judge Upholds State 340B Pharmacy Access Law

August 31 – A Colorado federal judge dismissed AstraZeneca's challenge to Colorado's S.B. 71, a law requiring drug manufacturers participating in the federal 340B program to provide discounted drugs through an unlimited number of contract pharmacies. The court held that the law is neither preempted by federal law nor unconstitutional.

Although the judge found that AstraZeneca had standing to sue, he rejected the plaintiff's claims that S.B. 71 conflicts with the federal 340B program, interferes with its enforcement scheme, increases participation costs in a way that triggers federal preemption, or violates federal patent law. The court also dismissed the company's constitutional claims, finding that the law does not violate the Contracts Clause by impairing pharmaceutical pricing agreements and does not constitute an unlawful taking because manufacturers voluntarily participate in the 340B program.

The ruling marks the third decision by a Colorado federal judge upholding S.B. 71 against challenges from drug manufacturers.

The case is AstraZeneca Pharmaceuticals LP v. Philip Weiser et al., number 1:25-cv-02685, in the U.S. District Court for the District of Colorado.

Drugmakers Challenge Illinois Law Protecting 340B Contract Pharmacy Access

August 7 – AbbVie Inc. and Novartis Pharmaceuticals filed separate lawsuits seeking to block Illinois' newly enacted H.B. 2371, which prohibits drug manufacturers from restricting 340B contract pharmacy arrangements. The law, which took effect immediately, bars manufacturers from interfering with covered entities' ability to have discounted 340B drugs delivered to contract pharmacies, including pharmacies

located outside Illinois, and limits the additional data manufacturers can require to process 340B purchases.

The drugmakers argue that H.B. 2371 expands manufacturers' obligations beyond those required under the federal 340B program and is therefore preempted by federal law. AbbVie further contends that the law constitutes an unconstitutional taking of private property. Novartis additionally argues that the statute violates the Dormant Commerce Clause by regulating conduct beyond Illinois' borders and unlawfully discriminates against manufacturers participating in the 340B program. Both companies seek to block enforcement of the law.

The cases are AbbVie Inc. et al. v. Raoul, number 1:26-cv-09523, and Novartis Pharmaceuticals Corp. v. Raoul, number 1:26-cv-09522, both in the U.S. District Court for the Northern District of Illinois.

Appeals Court Affirms HHS Must Approve 340B Rebate Mechanisms Before Implementation

July 21 – The U.S. Court of Appeals for the District of Columbia Circuit upheld a lower court ruling that Section 340B requires HHS to establish and approve a rebate mechanism before drug manufacturers may replace upfront discounts with rebate models.

The decision affirms a 2025 ruling that the Health Resources and Services Administration (HRSA) acted within its authority when it told several drugmakers they could not unilaterally implement rebate models while the agency continued reviewing the proposals. The case arose from multiple lawsuits brought by manufacturers challenging the agency's position, which were consolidated by the D.C. Circuit on appeal.

The case is Novartis Pharmaceuticals Corp. v. Robert Kennedy Jr. et al., number 25-5221, in the U.S. Court of Appeals for the District of Columbia Circuit.

Aimed Alliance is monitoring several additional cases relating to 340B drug pricing, including those listed below. We will report any dispositive developments in these matters in future editions of our *Litigation & Case Law Tracker*.

- **AbbVie Inc. v. Kennedy et al.**, number 1:26-cv-01190, in the U.S. District Court for the District of Columbia.
- **AbbVie Inc. et al. v. Murrill**, number 24-30645, in the U.S. Court of Appeals for the Fifth Circuit.
- **Pharmaceutical Research and Manufacturers of America v. Anthony G. Brown et al.**, number 24-1978, in the U.S. Court of Appeals for the Fourth Circuit.
- **Pharmaceutical Research & Manufacturers of America v. McCuskey et al.**, number 25-1054, in the U.S. Court of Appeals for the Fourth Circuit.

- **Pharmaceutical Research and Manufacturers of America v. Nerohna**, number 26-1039, in the U.S. Court of Appeals for the First Circuit.
- **University of Michigan Hospitals and Health Centers et al. v. CVS Health Corp. et al.**, number 2:26-cv-11618, in the U.S. District Court for the Eastern District of Michigan.

Health Insurers and Pharmacy Benefit Managers

Independence Blue Cross Enters $22.5M Settlement to Resolve DOJ Case

September 30 – The DOJ announced that Pennsylvania health insurer Independence Blue Cross has agreed to pay $22.5 million to resolve the government's claims that the insurer violated the False Claims Act (FCA). Originally filed in November 2020 under the FCA's whistleblower provisions, the lawsuit alleged that the insurer submitted inaccurate and false diagnosis codes for its Medicare Advantage Plan enrollees to improperly retain overpayments from Medicare.

The case is United States ex rel. Crawford v. Independence Blue Cross, number 2:20-cv-5818, in the U.S. District Court for the Eastern District of Pennsylvania.

Aetna Escapes Providers' Antitrust "Repricing" Suit

September 30 – The U.S. District Court for the District of Massachusetts granted Aetna's motion to dismiss a second amended complaint against it that alleges the insurer used Zelis Healthcare's repricing tools to unlawfully reduce provider reimbursements. The court found that the amended complaint failed to state a claim against Aetna. In the order, the judge stated "[w]henever the Complaint discusses the use of Zelis's repricing tools, it does so in qualified and ambiguous terms that stop short of alleging that Aetna entered into repricing agreements with Zelis." The order instructed the plaintiffs and the commercial payer defendants to meet and confer, and file a status report regarding any deficiencies in the pleadings identified by the court's memorandum and order that may affect claims against other individual commercial payer defendants. It added that the plaintiffs may seek leave to amend the second amended complaint to rectify any identified deficiencies.

The case, first filed in March 2025, involves consolidated lawsuits by doctors and other health care professionals against several large health insurers, the technology company Zelis, and Zelis' affiliates, alleging that companies conspired to suppress out-of-network payments using Zelis's proprietary analytical tools.

The case is In re: Zelis Repricing Antitrust Litigation, number 1:25-cv-10734, in the U.S. District Court for the District of Massachusetts.

A previous summary of this case can be found in the April 2026 edition of our *Litigation & Case Law Tracker*.

Judge Lets Blue Shield Mental Health Provider Directory Lawsuit Proceed

September 23 – A California federal judge largely refused to dismiss a proposed class action alleging that Blue Shield of California maintained a grossly inaccurate directory of mental health providers, including physicians and therapists who were unavailable or not accepting new patients. The court found that subscribers plausibly alleged Blue Shield failed to provide timely, accessible, in-network mental health care as promised under their plans, resulting in treatment delays and the loss of benefits for which they paid. The ruling allows claims for breach of contract, unfair competition, improper denial of benefits under ERISA, breach of fiduciary duty under ERISA, and violations of ERISA's mental health parity requirements and the Mental Health Parity and Addiction Equity Act to proceed.

The case is Jenniffer Roiz et al. v. Blue Shield of California Life & Health Insurance Co. et al., number 3:25-cv-09978, in the U.S. District Court for the Northern District of California.

PCMA Refiles Challenge to California PBM Fiduciary Duty Statute After Dismissal

September 10 – A California federal judge dismissed, with leave to amend, a lawsuit by the Pharmaceutical Care Management Association (PCMA) challenging a state law that imposes fiduciary duties on pharmacy benefit managers (PBMs) when administering ERISA-regulated employee benefit plans. PCMA argued that Senate Bill 41 is preempted by ERISA and sought to block its enforcement. While the court found that PCMA had articulated a plausible theory of injury based on the alleged ERISA conflict, it ruled that the trade group failed to allege sufficient facts showing that its members had suffered or faced a concrete injury necessary to establish standing. PCMA filed an amended complaint on August 14, and the defendants moved to dismiss the revised pleading on September 10.

The case is Pharmaceutical Care Management Association v. Rob Bonta et al., number 2:26-cv-00012, in the U.S. District Court for the Central District of California.

Caremark Becomes Second PBM To Settle FTC Suit Over Insulin Pricing

July 14 – The Federal Trade Commission (FTC) announced a settlement with Caremark Rx, a subsidiary of CVS Health Corporation and one of the nation's largest PBMs, and an affiliated entity, Zinc Health Services, LLC. According to the announcement, the settlement requires the PBM to adopt certain changes to its business practices intended to drive down patients' out-of-pocket costs, increase transparency, and ensure fair treatment of community pharmacies. Additionally, the settlement "locks in place up to $8.5 billion in consumer savings over the next 10 years and unlocks up to $4.5 billion in additional savings for patients over the same 10-year period from point-of-sale rebates."

The FTC brought an administrative action in September 2024 against the nation's three largest PBMs and their affiliated group purchasing organizations, alleging that they artificially inflated the list price of insulin medications by using anticompetitive and unfair rebating practices, and impaired access to lower-cost products. The settlement resolves the Commission's case with respect to Caremark and Zinc Health. The FTC reached a similar settlement with Express Scripts in February 2026. The Commission's case against Optum has been withdrawn from adjudication as the parties finalize the terms of a settlement.

The case is In the Matter of Caremark Rx et al., docket number 9437, before the Federal Trade Commission.

ERISA Class Action Challenges UnitedHealthcare's Copay Accumulator Practices

September 30 – An individual filed a lawsuit, individually and on behalf of a proposed class, challenging UnitedHealthcare's (UHC) refusal to count manufacturer copay assistance toward his deductible and annual out-of-pocket limit. According to the complaint, beginning January 1, 2026, UHC implemented a policy under which manufacturer copay assistance would not count toward enrollees' deductibles or annual out-of-pocket limits. The plaintiff alleges improper denial of benefits and breach of fiduciary duty under ERISA and seeks reimbursement for amounts allegedly paid twice and a declaration requiring UHC to credit qualifying third-party payments toward applicable cost-sharing requirements.

The case is Heinz v. United Healthcare Insurance Company Inc., No. 3:26-cv05, in the U.S. District Court for the District of Connecticut.

Aimed Alliance is monitoring several additional cases relating to health insurers and PBMs, including those listed below. We will report any dispositive developments in these matters in future editions of our *Litigation & Case Law Tracker*.

- **Eli Lilly and Company v. DrugPlace Inc. (FL) et al.**, number 1:26-cv-23516, in the U.S. District Court for the Southern District of Florida.
- **Express Scripts Inc., et al. v. Richmond, et al.**, number 25-2529, in the U.S. Court of Appeals for the Eighth Circuit.
- **Gene B. Lokken et al. v. UnitedHealth Group Inc. et al.**, number 0:23-cv-03514, in the U.S. District Court for the District of Minnesota.
- **Plumbers' Welfare Fund, Local 130 U.A. v. Express Scripts et al.**, number 1:26-cv-01718, in the U.S. District Court for the Northern District of Illinois.
- **Protecting Access to Retail Pharmacy LLC v. Prime Therapeutics LLC**, number 2:26-cv-02335, in the U.S. District Court for the Western District of Washington.
- **Wolf, et al. v. Accredo Health Group, Inc., et al.**, number 1:26-cv-00098, in the U.S. District Court for the Northern District of Illinois.

Patient Privacy

Pixel Suit Against Express Scripts Voluntarily Dismissed

October 16 – The U.S. District Court for the Northern District of California entered a stipulation of dismissal showing that the plaintiff voluntarily dismissed a lawsuit alleging Express Scripts allowed Meta to intercept users' health information through Meta Pixel tracking technology on the Express Scripts platform. The order states that the claims filed by the individual plaintiff were dismissed without prejudice, meaning that the individual plaintiff cannot refile the same claims against the defendant at a

later time. The putative class action claims were dismissed without prejudice, preserving the class's right to refile its claims. No other information was provided in the order.

The case is Lynch v. Express Scripts Holding Co., number 4:23-cv-01170, in the U.S. District Court for the Northern District of California.

A previous summary of this case can be found in the July edition of our *Litigation & Case Law Tracker.*

FTC, Two States Claim Hims & Hers Unlawfully Shares Health Data and Misleads Consumers

July 29 – The FTC, state of California, and Utah Division of Consumer Protection sued Hims & Hers in the Northern District of California, alleging that the company shared consumers' sensitive health information without their consent to third-party advertising platforms, including Meta. The complaint also alleges that Hims & Hers "misled hundreds of thousands of consumers by charging them for unwanted prescription medication subscriptions without their express informed consent." The plaintiffs assert violations of the Federal Trade Commission Act, Utah's Consumer Sales Practices Act, and California's False Advertising Law and Unfair Competition Law.

The case is Federal Trade Commission et al. v. Hims & Hers Health Inc., number 3:26-cv-07871, in the U.S. District Court for the Northern District of California.

Federal Court Allows Most of Portal Privacy Case Against Cigna to Proceed

July 27 – The U.S. District Court for the Eastern District of Pennsylvania largely allowed a second amended complaint against The Cigna Group and Cigna Corporate Services, LLC to survive. The plaintiffs, a group of Cigna health plan participants, allege that the insurer embedded tracking pixels and session-replay technologies on its public website and secure member portal, causing users' health care-related information, searches, and portal activity to be transmitted to third-party marketing and analytics companies without proper consent.

The court found it plausible that information collected through the secure member portal qualified as HIPAA-protected health information and that Cigna may have disclosed it for marketing purposes without the written authorization required by HIPAA and Cigna's own privacy notices. As a result, the court permitted claims under the federal Wiretap Act, Pennsylvania's wiretap statute, breach of fiduciary duty, and unjust enrichment to proceed. However, it dismissed the plaintiffs' intrusion-upon-seclusion claim, concluding that Cigna itself was the intended recipient of information users voluntarily submitted through its website and therefore could not be liable for intruding upon communications directed to it. The ruling comes after the court dismissed most of the plaintiffs' original complaint in February on grounds that they consented to the alleged disclosures.

The case is Adair et al. v. Cigna Corporate Services LLC et al., number 2:25-cv-02384, in the U.S. District Court for the Eastern District of Pennsylvania.

Aimed Alliance is monitoring the following additional cases relating to patient privacy. We will report any dispositive developments in these matters in future editions of our *Litigation & Case Law Tracker*.

- **C.B. et al. v. Planned Parenthood Federation of America, Inc. et al.**, number 1:26-cv-05201, in the U.S. District Court for the Southern District of New York.
- **In re Blue Shield of California Privacy Litigation**, number 4:25-cv-03209, in the U.S. District Court for the Northern District of California.



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