

**April 30, 2025**

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, caregivers, and providers. This quarterly publication also highlights the judicial-branch advocacy efforts of Aimed Alliance and other not-for-profit organizations.

We welcome feedback at [policy@aimedalliance.org](mailto:policy@aimedalliance.org).

## **Judicial-Branch Advocacy**

### **Fourth Circuit Accepts Not-for-Profit Advocates' Amicus Briefs**

April 8, 2025 – The U.S. Court of Appeals for the Fourth Circuit accepted amicus briefs from not-for-profit organizations Community Oncology Alliance and The Pioneer Institute. The briefs support a federal district court's preliminary injunction against a West Virginia law that restricts drug makers' ability to audit hospitals and other health care providers that purchase prescription medications at discounted prices under the federal 340B program.

The consolidated cases are *Pharmaceutical Research and Manufacturers of America v. McCuskey, et al.*, No. 25-1054(L); *AbbVie Incorporated et al. v. McCuskey et al.* No. 25-1055; and *Novartis Pharmaceuticals Corporation, et al. v. McCuskey, et al.*, No. 25-1056, in the U.S. Court of Appeals for the Fourth Circuit.

## **Federal Policy Challenges**

### **Appeals Court Rebukes Administration for Disregard of Due Process and Supreme Court Order**

April 17, 2025 – A three-judge panel of the U.S. Court of Appeals for the Fourth Circuit denied the federal government's motions to stay an injunction in the case surrounding Kilmar Abrego Garcia, a Maryland resident originally from El Salvador who was deported to a Salvadoran prison without due process. Due process is a constitutional right that ensures the government follows certain procedures when depriving someone of life, liberty, or property.

The Court did not address whether the government had a correct legal basis to deport Mr. Abrego Garcia, but rather stated the government was required to follow certain procedures when doing so, and it did not. As such, the Fourth Circuit affirmed the Supreme Court's order requiring the federal government to "facilitate" the return of Mr. Abrego Garcia from El Salvador.

While this case is not specifically related to health policy, it is notable because the judicial branch plays a key role in our checks-and-balances system. If the federal government continues to refuse to comply with court orders from the judicial branch, these checks-and-balances could diminish and have Implications for other Issues like health care access and affordability.

The case is Kilmar Armando Abrego Garcia, et al. v. Kristi Noem, Secretary of Homeland Security, et al., No. 25-1404.

### **Federal Court Pauses Cuts in Health Care Funding for States**

April 3, 2025 – The U.S. District Court for Rhode Island temporarily barred the Trump administration from moving forward with the termination of grants supporting state public health programs. The Department of Health and Human Services (HHS) terminated the public health funding "for cause" because "the grants and cooperative agreements were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grants and cooperative agreements are no longer necessary as their limited purpose has run out."

The temporary restraining order required HHS to maintain the status quo until the Court decides whether the States' motion for a preliminary injunction will be granted. In the meantime, HHS is "fully restrained from implementing or enforcing funding terminations that were issued to Plaintiff States ... for reasons related to the end of the COVID-19 pandemic."

The case is State of Colorado, et al. v. U.S. Department of Health and Human Services, et al, No. 1:25cv121.

### **Two Developments Could Discourage Challenges to Federal Policies**

March 14, 2025 – Two recent developments could make litigation costs higher for parties challenging federal policies. First, the Trump Administration issued a memorandum titled [Ensuring the Enforcement of Federal Rule of Civil Procedure 65\(c\)](#) and a related [executive order](#), seeking to require federal policy challengers to post bond in preliminary injunction cases. This change may make it more difficult for potential plaintiffs to challenge federal laws and policies if they don't have the financial resources to post the required bond.

Second, the Supreme Court recently decided *Lackey v. Stinnie*, No. 23–621, which could make it more difficult for some challengers to recover attorneys’ fees after a preliminary injunction is granted. The Supreme Court ruled 7-2 that plaintiffs who obtain only preliminary injunctive relief before a case becomes moot do not qualify as “prevailing parties” eligible for attorney fees. The Court explained that a party must receive judicial relief that conclusively resolves the party’s claims on the merits to qualify for attorney fees.

### **Supreme Court Hears Arguments In Preventive Health Care Coverage Case**

April 21, 2025 – The U.S. Supreme Court heard oral arguments in a case challenging the constitutionality of the Affordable Care Act’s preventive health care coverage requirement. In 2022, the U.S. District Court for the Northern District of Texas ruled that the U.S. Preventive Services Task Force (USPSTF) lacked authority to mandate private insurance coverage of preventive health care services because its members were not appointed by the President or confirmed by the Senate. The U.S. Court of Appeals for the Fifth Circuit upheld the decision, finding the members of the USPSTF were unconstitutionally appointed principal officers of the U.S. government.

The Supreme Court will decide whether USPSTF members are inferior or principal officers, a distinction central to the Appointments Clause argument against the preventive health care coverage requirement. The Supreme Court is expected to issue its opinion in late June or early July.

The decision could significantly impact healthcare, potentially removing insurance coverage for over 30 preventive health care services, including those in HIV, oncology, and mental health care.

The case *Robert F. Kennedy, Jr., Secretary of Health and Human Services, et al. v. Braidwood Management, Inc., et al.*, No. 24-316 in the U.S. Supreme Court. In the lower courts, prior to the change in executive administration, the case was named *Braidwood Management Inc., et al. v. Xavier Becerra, et al.*

## **Alternative Funding Providers**

### **Court Denies Preliminary Injunction Against Alternative Funding Provider**

April 14, 2025 – The U.S. District Court for the Northern District of Illinois denied pharmaceutical company AbbVie’s motion for a preliminary injunction against alternative funding provider Payer Matrix. In a discussion of Payer Matrix’s activities related to AbbVie’s patient assistance program (PAP), the court explained that the defendant’s CEO testified under oath as to the following:

That Payer Matrix's PAP-related practices with respect to AbbVie ended as of May 2023, that corporate policy is that Payer Matrix's RCCs are not to assist members with PAP applications, that Payer Matrix's IT team has now made it impossible for an RCC to create an AbbVie PAP application in their system, and that Payer Matrix has collected no cost avoidance fees for any newly submitted PAP applications to AbbVie since July 2023.

The court ruled that AbbVie failed to persuasively establish that AbbVie would experience irreparable harm in the absence of a preliminary Injunction.

AbbVie's underlying lawsuit against Payer Matrix continues. AbbVie has alleged Payer Matrix misconduct surrounding AbbVie's PAP and copay assistance program, drug switching, and international drug sourcing.

The case is AbbVie Inc. v. Payer Matrix LLC, No. 1:23-cv-02836.

### **Court Denies Motion To Declare Speaker's Statements Defamatory Per Se**

February 3, 2025 – The U.S. District Court for the Eastern District of Pennsylvania denied Paydhealth, LLC's motion to file a second amended complaint in its defamation case against Dawn Holcombe. Paydhealth describes itself as "an advocate to individual workers" that "helps them navigate" patient assistance programs. Ms. Holcombe is a healthcare consultant and frequent public speaker. Paydhealth alleges that Ms. Holcombe "published and has continued to republish defamatory statements accusing Paydhealth of business misconduct."

In denying Paydhealth's motion, the court explained:

The relief sought would have this Court declare Ms. Holcombe's speech defamatory per se which would, in effect, enjoin her free speech into the future and prohibit her from the speech that Plaintiff alleges to be defamatory. If the Court were to do that, the Court would then have usurped the role of a jury by making its own determination that, in fact, her speech is defamatory, thus violating the Defendant's Constitutional right to a jury trial.

The case is Paydhealth, LLC v. Dawn G. Holcombe, d/b/a DGH Consulting, No. 2:24-cv-00259.

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

- **Johnson & Johnson Health Care Systems, Inc. v. Save On SP, LLC; Express Scripts Inc.; and Accredo Health Group, Inc.**, No. 2:22-cv-02632 in the U.S. District Court for the District of New Jersey.
- **Sharx, LLC v. AbbVie Inc.**, No. 2024-L-000264 in the Circuit Court of Cook County, Illinois.
- **Gurwitch v. Save On SP LLC**, No. 1:25-cv-00006 in the U.S. District Court for the Western District of New York.

## Compounding

### FDA Defends Drug Shortage Decision

April 9, 2025 – In a legal brief asking the U.S. District Court for the Northern District of Texas to grant summary judgment in its favor, the Food and Drug Administration (FDA) argued that it properly determined that the national tirzepatide shortage was resolved. Tirzepatide injection products are approved to treat type 2 diabetes, obesity, and sleep apnea. The FDA’s brief explained:

Ordinarily, the Federal Food, Drug, and Cosmetic Act (FDCA) restricts the compounding of drugs that are essentially copies of FDA-approved drugs. When FDA determines that there is a nationwide shortage of a particular drug, however, the FDCA allows, during the shortage, certain compounding that it would otherwise restrict. Correspondingly, once FDA finds the shortage no longer exists, the FDCA’s temporary allowance of such compounding ends ...

Plaintiffs, a trade association for drug compounders and a pharmacy engaged in compounding, challenge the factual and legal bases for FDA’s December 2024 determination that the shortage is resolved. None of their objections has merit ...

FDA applied the plain meaning of the statute to determine whether a nationwide shortage existed.

The case is Outsourcing Facilities Association, et al. v. U.S. Food and Drug Administration, et al., and Eli Lilly and Company, No. 4:24-cv-00953 in the U.S. District Court for the Northern District of Texas.

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

- **Eli Lilly and Company v. Alderwood Surgical Center LLC, et al.**, No. 2:24-cv-00878 in the U.S. District Court for the Western District of Washington.
- **Eli Lilly and Company v. Empower Clinic Services, LLC, d/b/a Empower Pharmacy et al.**, No. 2:25-cv-02183 in the U.S. District Court for the District of New Jersey.
- **Eli Lilly and Company v. Strive Pharmacy LLC**, No. 1:25-cv-00401 in the U.S. District Court for the District of Delaware.

## Counterfeits

### Supplement Maker Wins Damages, Injunction Against Sellers of Counterfeit Products

April 3, 2025 – The United States District Court for the Western District of Washington awarded Quincy Bioscience and Amazon.com nearly \$1.9 million in damages against defendants who sold counterfeit Prevagen-branded brain health products on Amazon.com. The court issued a default judgment and permanent injunction after the sellers, mostly residents of Kenya, failed to participate in the case.

The case is Amazon.com Inc. et al. v. Nyutu et al., No. 2:23-cv-01681.

## Drug Importation

### Executive Order Directs FDA To Make It Easier for States To Import Canadian Drugs

April 15, 2025 – President Trump signed an [executive order](#) directing the Food and Drug Administration (FDA) "to make it easier for States to obtain approval" to import drugs from Canada. As explained in [Aimed Alliance's 2024 citizen petition](#) to the FDA, seven states (Colorado, Florida, Maine, New Hampshire, New Mexico, Texas, and Vermont) have enacted laws to establish a drug importation program, but Florida is the only state that has obtained FDA approval of its program. This executive order has been released at the same time the Department of Commerce is seeking feedback on how tariffs on pharmaceutical products may impact consumers.

## Drug Price Caps

### Federal Court Dismisses Challenge to Colorado Drug Price Cap Law

April 14, 2025 – The U.S. District Court for the District of Colorado dismissed a case challenging the constitutionality of Colorado's law establishing a "Prescription Drug

Affordability Review Board” and prescription drug price caps. The court ruled that the plaintiffs, a prescription drug manufacturer and patent licensees, are not subject to “direct regulation” under the law and, therefore, do not have standing to sue. The court explained that the price caps set under the Colorado law “do not apply at the pharmaceutical manufacturer’s point of sale” and apply only to “downstream transactions for the actual sales and reimbursements of the prescription drug dispensed to Colorado consumers.” On April 14, the plaintiffs filed a notice of appeal.

The case is Amgen Inc. v. Colorado Pres. Drug Affordability Review Board, No. 2025-1641 in the U.S. Court of Appeals for the Federal Circuit.

Aimed Alliance is monitoring numerous additional cases, including the three combined cases listed below, relating to drug price caps. We will report any substantive developments in these matters in future editions of our *Litigation & Case Law Tracker*.

- **Bristol Myers Squibb Co. v. Secretary United States Department of HHS**, No. 24-01820 in the U.S. Court of Appeals for the Third Circuit.
- **Janssen Pharmaceuticals Inc. v. Secretary United States Department of HHS, et al.**, No. 24-01821 in the U.S. Court of Appeals for the Third Circuit.
- **Novo Nordisk, Inc., et al. v. Secretary United States Department of HHS, et al.**, No. 24-2510 In the U.S. Court of Appeals for the Third Circuit.

## 340B Drug Pricing

In addition to Pharmaceutical Research and Manufacturers of America v. McCuskey, et al., discussed in the Judicial-Branch Advocacy section above, Aimed Alliance is monitoring the following cases relating to state laws affecting the federal 340B drug pricing program. We will report any substantive developments in these matters in future editions of our *Litigation & Case Law Tracker*.

- **AbbVie Inc., et al. v. Fitch**, No. 24-60375, in the U.S. Court of Appeals for the Fifth Circuit.
- **AbbVie Inc., et al. v. Jackley, et al.**, No. 3:25-cv-30006 in the U.S. District Court for South Dakota.
- **AbbVie Inc., et al. v. Wrigley, et al.**, No. 1:25-cv-00081 in the U.S. District Court for North Dakota.

## **Health Privacy**

### **Consumers File Health Privacy Suit Against Meta**

April 15, 2025 – The plaintiffs in a class action lawsuit in the U.S. District Court for the Northern District of California filed an amended complaint against Meta Platforms, Inc. (Facebook’s parent company). The complaint alleges that the plaintiffs, who had chosen not to create or maintain Facebook accounts, “had a broad array of identifiable health information, including their name, contact information, account creation information, and mental health questionnaire answers, transmitted while using the services of a telehealth company. Plaintiffs were not aware that their information was being sent to Meta, and they did not at any point consent to its transmission.”

The case is H., et al. v. Meta Platforms, Inc., No. 3:23-cv-4784.

### **Online Privacy Case Against Health System May Proceed**

March 7, 2025 – The U.S. District Court for the Middle District of Florida declined to dismiss five out of six claims against a Florida hospital system for allegedly sharing patients’ private information with tech giants through ad tracking software. The court dismissed an invasion of privacy claim without prejudice, meaning the plaintiff may amend her complaint to replead that claim.

The case is W.W. v. Orlando Health Inc., No. 6:24-cv-1068.

## **Pharmacy Benefit Managers**

### **FTC Pauses Case Against PBMs**

April 4, 2025 – The Federal Trade Commission paused administrative lawsuit against three pharmacy benefit managers (PBMs) on March 31 for at least 105 days. The FTC complaint accuses the PBMs of inflating insulin prices through anticompetitive rebate schemes.

The agency did not have a quorum of commissioners to hear the matter after two Republican commissioners recused themselves and two Democratic commissioners were removed from their posts by President Donald Trump. On April 3, FTC Chair Andrew Ferguson withdrew his recusal from the proceedings. It is unclear how Ferguson’s decision to join the case will affect the timeline.

The case is Caremark Rx, Zinc Health Services, et al., In the Matter of (Insulin), FTC Docket Number 9437.



## Provider Payments

### Federal Government Weighs In on Health Insurers' Common Pricing Algorithm

The federal government filed a statement of interest in federal multidistrict litigation surrounding health insurers' payment rates for out-of-network health care providers' services. The government discussed the legal framework for analyzing claims involving competitors' "use of algorithmic technologies to coordinate their decision-making," which "poses a growing threat" to free-market competition.

The case is In re: MultiPlan Health Insurance Provider Litigation, MDL number 3121, in the U.S. District Court for the Northern District of Illinois.



1455 Pennsylvania Avenue NW, Suite 400, Washington, DC 20004

202-349-4089 • [AimedAlliance.org](https://AimedAlliance.org)

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