Bloomberg Law News 2024-08-07T08:26:45815950413-04:00

Pharma Industry Ramps Up Legal Fight of State Drug Discount Laws

By Nyah Phengsitthy 2024-08-07T05:05:44000-04:00

- Drugmakers, trade group have filed at least 23 lawsuits
- State laws prohibit restrictions to certain pharmacies

Pharmaceutical industry giants are ramping up a fight against state laws that require them to distribute discounted drugs to an unlimited number of pharmacies, piling up lawsuits that are now pending across the US.

Drugmakers Novartis AG, AstraZeneca PLC, AbbVie Inc., and trade group Pharmaceutical Research and Manufacturers of America have filed a combined 23 lawsuits against eight recently enacted state laws that prohibit the companies from restricting the supply of discounted drugs to certain pharmacies under the federal 340B Drug Pricing Program.

Manufacturers under the program are required to discount drugs to qualifying health providers, known as covered entities, that treat low-income and uninsured patients. Providers contract with pharmacies to dispense discounted drugs to covered entities that don’t have an in-house pharmacy, but manufacturers in recent years have limited or restricted shipments to some, alleging unlawful practices.

Over a dozen states have introduced 340B contract pharmacy arrangement protection laws to combat such restrictions, but the passage of legislation over the past two months has prompted various drugmaker challenges.

“Every state where this is enacted right now is currently in litigation over whether these contract pharmacy laws can be in place,” said Brandon Shirley, senior counsel at Krieg DeVault LLP. “Each side is getting their version of the facts in front of judges on how this program operates as each side seems to have a different and compelling story to tell about the program.”

The industry has yet to see a ruling in its favor as federal courts so far have sided with the states, but the recently filed lawsuits could change the course as they allege a new host of claims including

violations of federal law, patent exclusivities, and compelled speech. PhRMA at the end of July filed a petition for a writ of certiorari before the US Supreme Court, asking the justices to review its case against Arkansas' law.

Notably, the state laws have resulted in manufacturers pulling back on restrictions, according to letters and policy statements from the industry tracked by 340B ESP. Manufacturers failing to comply with state laws are subject to hefty penalties, with some states issuing a fine of $50,000 per violation for each package of drugs.

"These rulings do change manufacturer behavior," Shirley said. "Even though they're contesting and fighting, they are still lifting these restrictions when states have passed these laws."

Preemption, Patents, and Speech

The crux of drugmaker complaints allege the state laws violate the supremacy clause of the US Constitution and are preempted under the federal 340B statute.

The program is entirely federal as it's "inextricably linked" to Medicaid and to Medicare Part B, the drug industry says.

But that preemption claim has so far been rejected by a few judges.

The US Court of Appeals for the Eighth Circuit in March held that Arkansas' Act 1103—a law prohibiting manufacturers from cutting off contract pharmacies—is constitutional and "does not create an obstacle for pharmaceutical manufacturers to comply with 340B."

The decision fuels states' argument that the laws aren't preempted and it's within their police powers to regulate the health and safety of their residents.

Arkansas and Louisiana were the two states to have such laws passed for over a year, while states including Kansas, Maryland, Minnesota, Mississippi, Missouri, and West Virginia, enacted bills in recent months.

The recently passed bills have resulted in new lawsuits from the pharmaceutical industry.

Drugmakers and PhRMA in the latest round of litigation tacked on new arguments against states that went beyond federal preemption. They pushed back on the Eighth Circuit because it “concluded that '[c]overed entities maintain title to the 340B drugs,’ and the ‘pharmacy becomes an agent of the covered entity.’”

“That is not true in Missouri,” AbbVie said to the state in July. “Covered entities do not maintain title to 340B-discounted drugs provided to contract pharmacies, nor do contract pharmacies serve as the ‘agent of the covered entity.’”

Claims now range from violations of federal patent laws and regulatory exclusivity periods for drug products to violations of the Fifth Amendment takings clause and the First Amendment free speech clause.

“We have these manufacturers who are looking at a second bite at the apple,” said Barbara Williams, principal at Powers, Pyles, Sutter & Verville PC.

Despite the state success at the Eighth Circuit, that case only ruled on preemption, which leaves the door open for courts to analyze the various other drugmaker claims, Williams said.

But the industry so far hasn’t swayed other courts with its arguments.

Judge Halil Suleyman Ozerden of the US District Court for the Southern District of Mississippi denied preliminary injunctions in July in separate lawsuits filed by Novartis and PhRMA, writing plaintiffs haven’t shown a “substantial likelihood of success on the merits as required to obtain a preliminary injunction.”

Mississippi’s law “plainly falls under the umbrella of a health and safety regulation,” and “the state statute therefore triggers the presumption against preemption,” Ozerden wrote in both orders.

Requests for preliminary injunctions filed by other manufacturers are also pending before courts other states.

A Wide Circuit Range

The various lawsuits filed are likely to open the door to a future circuit split, some legal experts say.

While two cases are pending before the US Court of Appeals for the Fifth Circuit on rejected preliminary injunctions, other cases could head to the US Court of Appeals for the Fourth Circuit and the US Court of Appeals for the Tenth Circuit.

“We’ll have to see if other courts take the same approach as the Eighth Circuit,” said Jeffrey Davis, member at Bass, Berry, & Sims PLC. “But I do think that the experience in Arkansas shines a light on this as a potential path.”

The industry, though, is underscoring rulings from the US Court of Appeals for the Third Circuit and the US Court of Appeals for the District of Columbia.

PhRMA in its petition to the high court said the Eighth Circuit decision is conflicting because two other appeals courts ruled the 340B statute doesn’t prohibit drug manufacturers from imposing any conditions on the distribution of discounted drugs to covered entities.

Manufacturers point to those other appeals court rulings as support, backing their stance that the federal program doesn’t curb their ability to limit legally mandated deliveries of steeply discounted drugs to contract pharmacies.

But while those other appeals courts largely found in favor of manufacturers, they also recognize the manufacturers’ obligation to offer the 340B prices, Davis said.

“There are a lot of instances—because of drug manufacturers’ limited distribution networks or payer restrictions on pharmacy network access—where a covered entity may not have access to a drug,” he said.

“In order for the manufacturer to keep its obligation under the 340B law, the appeals courts meant we need to recognize contract pharmacy arrangements because otherwise the manufacturer is not meeting its obligation to offer 340B prices.”

A pending decision from the US Court of Appeals for the Seventh Circuit also remains on the issue of contract pharmacy restrictions, where Eli Lilly & Co. and HRSA battle over whether Congress gave the agency authority to require drugmakers ship steeply discounted products to for-profit pharmacies.

To contact the reporter on this story: Nyah Phengsitthy in Washington at nphengsitthy@bloombergindustry.com

To contact the editors responsible for this story: Zachary Sherwood at zsherwood@bloombergindustry.com; Karl Hardy at khardy@bloomberglaw.com

Related Articles

Drug Lobby Dealt Setback Over Arkansas Contract Pharmacy Law (1)

States Guard Drug Discount Program as Pharma Wages Legal Battles

Eighth Circuit Rejects PhRMA Full Review in Drug Discount Suit

Novartis, PhRMA Sue West Virginia Over Contract Pharmacy Law

Novartis, PhRMA Lose Bid to Block Mississippi Drug Pharmacy Law

Drugmakers Defeat Health Agency in 340B Drug Discount Row (2)

Novartis, United Therapeutics Defeat US on Discount Drug Limits

PhRMA Seeks Supreme Court Review on State Discount Drug Limits

Eli Lilly, HHS Highlight Contrasts in Drug Discount Legal Row (1)