

As a competitor encroached, Mylan took one state to court to push EpiPen sales, documents show

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The pharmaceutical company Mylan has developed a reputation for fighting tooth-and-nail to promote its flagship product, the EpiPen.

Mylan has contended that its intensive marketing efforts save lives. But over the past year, the public has started to question whether the company's business tactics are in line with the best interests of patients.

Now STAT has learned of yet another previously unreported legal maneuver employed by the company to force one state to drive even more sales to its EpiPen, an epinephrine auto-injector used to halt potentially life-threatening allergic reactions.

The case played out in West Virginia when the state tried to save taxpayers an estimated \$1 million by encouraging doctors to prescribe an alternative to the EpiPen. In a 2015 lawsuit that escaped public attention until now, Mylan sued the state to halt the changes.

Hundreds of pages of court documents examined by STAT detail an effort by Mylan to compel the state to give the EpiPen coveted "preferred" status among its Medicaid drug offerings, which West Virginia had decided to give to a different epinephrine auto-injector instead.

That status would mean that the device would be paid for by Medicaid, no questions asked, while Medicaid recipients would have to get special approval for coverage of different devices.

Three lawyers who reviewed the case at the request of STAT said they could not think of another instance when a pharmaceutical company sued to protect the status of its medication on a state formulary.

“This is another really good example of how Mylan has attempted to use the law to their advantage at every turn to expand their market share,” said Rachel Sachs, an associate professor at the Washington University in St. Louis School of Law who specializes in health law.

It’s another in a series of controversies that have dogged Mylan, which first entered the spotlight for [raising the price](#)³ of EpiPen by 450 percent since 2004. Since then the company has faced criticism for [allegedly overcharging](#)⁴ state Medicaid departments for the drug, [suing](#)⁵ a competitor who tried to introduce a generic EpiPen, and [offering](#)⁴ deeply discounted EpiPens to schools on the condition that they not purchase competing products.

Initially, Mylan’s lawsuit didn’t succeed — but then the company had a stroke of luck. The competing product was voluntarily taken off the market, and in its place, the EpiPen regained preferred status, which it maintained in West Virginia until this year.

Mylan declined to comment for this story.

Seeking coveted status

West Virginia’s experience is pertinent for the rest of the nation because the case dealt with an arcane but powerful pharmaceutical policy tool many states have. The tool, called a “preferred drug list,” is used by state Medicaid programs to keep drug costs down.

If multiple drugs treat the same condition, then states can pick some to put on the preferred list, which means that Medicaid will automatically pay for them. If a drug isn’t on the list, the patient needs to get “prior authorization” from the Medicaid program for it to be covered. The intention of these lists is to encourage doctors to prescribe the preferred products.

In order to secure this preferred status, drug companies offer states a discounted price — and if drugs are equally effective, then states often “prefer” the cheaper ones.

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[Mylan extends its EpiPen recall to the US and many other parts of the world](#)⁶

Pharmaceutical companies fought against these lists from the beginning. The Pharmaceutical Research and Manufacturers of America, the industry interest group, filed lawsuits seeking to prevent states from using preferred drug lists in the early 2000s, with at least [one suit](#)⁷ making it all the way up the Supreme Court. Decisions in the courts affirmed that it’s OK for states to establish such lists, which now most states maintain.

In the [winter of 2015](#)⁸, the committee of doctors, pharmacists, and health care professionals that determines that list in West Virginia voted to take the EpiPen off of the preferred list and replace it with the [Auvi-Q](#)⁹, an epinephrine auto-injector resembling a deck of cards that at the time was marketed by Sanofi. (It has since been re-introduced by Kaleo.) It has a speaker that gives voice instructions once it is removed from its case.

But just a few days before the change was scheduled to take place, Mylan filed a lawsuit against the secretary of the West Virginia Department of Health and Human Resources, [seeking to prevent](#)¹⁰ this modification to the list from going into effect.

“We believe that the [committee] made an improper illegal decision when it moved to replace the EpiPen with [the Auvi-Q],” an attorney for Mylan said before a West Virginia circuit court judge at a [hearing](#)¹¹ on March 31, 2015. Mylan argued that, even though the committee held an open meeting where it voted on the change, the real decision happened in private.

The state disagreed that any such decision was made behind closed doors, characterizing Mylan’s actions as purely profit-seeking.

“This action seeks to do one thing: Protect a pharmaceutical giant’s market share to the detriment of the West Virginia Medicaid program and create a monopoly over a specific class of drug in this State,” West Virginia’s attorneys argued in a [motion to dismiss](#)¹² the case.

Vicki Cunningham, West Virginia’s director of pharmacy services who is a nonvoting member of the committee that made the decision, said at the hearing that the state would save “right around a million dollars” because of the change. She did not specify whether those savings were one-time or annual.

“I believe Auvi-Q is a product that’s much more user-friendly, easier to carry on your person and have available in emergency, and considerably less expensive than EpiPen,” Cunningham said.

The West Virginia Department of Health and Human Resources declined to comment for this story.

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[Mylan may have violated antitrust law in its EpiPen sales to schools, legal experts say](#)⁴

Legal experts told STAT this would be a hard case for Mylan to win because judges often defer to the decisions of administrative committees.

“You’ve got to have a lot of money to bring a lawsuit when your prospects of victory are not that high,” said Bill von Oehsen, a Washington, D.C., lawyer who practices health law at Powers Pyles Sutter & Verville. “For me, that’s a sign that we’ve got pretty well-financed company here that they can pay for a lawsuit like this.”

Mylan sought a [“preliminary injunction,”](#)¹⁰ which would have forced the state to keep the EpiPen as a preferred drug while the company continued to litigate over the issue of the secret decision-making process. In order to achieve this, Mylan needed to prove that it would suffer “irreparable harm.”

The company argued that removing its drug from the list would cause harm by taking a bite out of its market share, and also by damaging its reputation — in the company’s home state — and putting patients at risk.

“If EpiPen is removed from the ‘preferred’ category... I believe that Mylan Speciality will experience harm to its reputation and loss of goodwill among patients and medical professionals,” said Roger Graham, the president of Mylan Specialty, the division of the company that markets the EpiPen, in a [sworn affidavit](#)¹³. “Among other things, I believe that at least some patients and medical professionals will transfer the anger and frustration resulting from this change to Mylan Specialty or EpiPen.”

Mylan also argued that patients might be harmed by this change.

Graham, in his sworn affidavit, said that “switching a patient from one [epinephrine auto-injector] to another risks confusing ingrained behaviors in the product’s administration and places the patient at risk during emergency situations.”

Just a few weeks after the hearing, a [published study](#)¹⁴ indicated that the opposite may be true — patients familiar with an older version of the EpiPen who tried to use an Auvi-Q in a simulated setting were actually more successful with the new device.

The day after the hearing, the judge issued an [order](#)¹⁵ denying Mylan's request for a preliminary injunction, saying that Mylan did not provide evidence that the decision was made in secret, and noting that states are better equipped than pharmaceutical companies, who have a vested financial interest, to choose which drugs to put on the preferred drug list.

In short order, Mylan appealed the case to the West Virginia Supreme Court of Appeals.

The case of Minnesota

Multiple lawyers who reviewed the case for STAT couldn't name another time a pharmaceutical company had sued to protect their state formulary status.

But there is evidence that Mylan was closely monitoring formulary changes in other states as well.

When, on April 22, 2015, the state of Minnesota announced a decision to move the EpiPen off of its preferred drug list in favor of the Auvi-Q, it cited price as the motivating factor.

"EpiPen products are at a significant price premium to other epinephrine auto-injectors that are just as effective and easy to use," the [update](#)¹⁶ reads.

In July, an attorney sent a [letter](#)¹⁷ on behalf of Mylan urging Minnesota to put EpiPen back in the preferred category, claiming that failure to do so may put patients at risk.

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[Mylan is sued by consumers who claim PBM rebates are really kickbacks](#)¹⁸

"I hope to resolve this issue amicably with [the state]," the attorney wrote on behalf of Mylan. "Please understand, however, that Mylan Specialty is prepared to take all appropriate action necessary to mitigate the health risk to Medicaid patients in Minnesota who are affected by [this] decision if we are unsuccessful in obtaining a reversal of [this] decision."

Representatives of Mylan later met with state officials, but the state didn't back down, keeping EpiPen off the preferred list, according to [documents](#)¹⁹ provided by the Minnesota Department of Human Services.

The department "is not aware of any action" by Mylan against them, a spokesperson said.

Feeling price pressure

These changes happened before any of the public outcry about the high price of EpiPens, which began last summer.

"The lawsuit itself shows that states have been dealing with these problems, and insurers have been dealing with these problems, for a lot longer," Sachs said. "Now patients have finally realized these are real concerns, but it just goes to show that states have been asking these questions and trying to figure out how to deal with them for quite some time."

Meanwhile, the Auvi-Q was having some troubles of its own. Twenty-six unconfirmed reports of the device not delivering the right amount of epinephrine led to the product being taken off the market in the fall of 2015.

Soon after, the legal appeals in West Virginia were [withdrawn](#)²⁰, and the case fizzled out. By the beginning of 2016, the EpiPen returned to being one of the state Medicaid program's preferred drugs in both Minnesota and [West Virginia](#)²¹.

In the years since, more and more state Medicaid programs have [moved](#)²² the EpiPen off of preferred status in the wake of outcry over the drug's price. As of [April 1, 2017](#)²³, the EpiPen is again deemed not preferred in the state of West Virginia.

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