

LAW369 2018 MVP Jay Lefkowitz

Kirkland & Ellis LLP partner Jay Lefkowitz convinced the Fourth Circuit that a Maryland drug pricing law violates the dormant commerce clause and is therefore unconstitutional, earning him a spot as one of *Law360*'s 2018 Life Sciences MVPs.

His biggest achievement this year:

As counsel for the generic drug lobby, the Association for Accessible Medicines, Lefkowitz persuaded the Fourth Circuit to invalidate a Maryland law targeting drug pricing. The law bars drug manufacturers or wholesale distributors from imposing unconscionable price increases on "essential" off-patent or generic prescription medications and authorizes \$10,000 penalties for each violation.

A district court had freed Maryland from the suit at the motion to dismiss stage, but the Fourth Circuit in April revived the case and ruled 2-1 in Lefkowitz's favor. At issue wasn't the ability to regulate drug prices, but whether the law reached too much into other states and violated the dormant commerce clause.

"It's such an interesting set of constitutional issues," he said. "Anytime you have a case involving the extraterritorial prong "I just became totally fascinated by the life sciences space ... [It] was ... an industry that I really gravitated to both because of the substance and because it's a heavily regulated industry and so it fit well with my skill set ... "

of the dormant commerce clause, you kinda feel like you're back in law school. It's a case that I think is of significant import, not only for the drug industry, but for the question of the role of state power and the limits on state power in our country."

Lefkowitz said the actual objective of the bill is fair but said Maryland went about it in the wrong way.

"The manner in which they've done it violates the Constitution because it regulates drug sales that take place entirely outside the state of Maryland," he said. "That's really going a step too far."

Maryland has appealed to the U.S. Supreme Court. Lefkowitz said he'll be staying on the case.

His biggest challenge:

Much of Lefkowitz's work involves so-called reverse payment or pay-for-delay cases between drugmakers, with at least half a dozen on his plate right now. The Supreme Court has given little guidance since its landmark FTC v. Actavis decision in 2013, so Lefkowitz said this is "a completely open area of the law." In that case, the justices held that reverse payment settlements can be subject to antitrust review.

"There's very little guidance and we haven't had a lot of track record," he said. "We've only had one case that's gone to a verdict: the Nexium case, where the defendants actually prevailed. But there's really very little guidance on how you litigate these cases, how you deal with the economics of the settlements and what would constitute protected conduct and what would constitute, according to the Supreme Court, potentially improper conduct."

"Working with the other litigants in these cases and working with the judges in these cases to try to map out ground rules for these cases has been a very significant challenge this year," he added.

In the Nexium case, Lefkowitz represented defendant Ranbaxy.

Why he's a life sciences attorney:

Lefkowitz said he became a life sciences attorney to make his mom proud.

"I wasn't good enough with biology to actually become a doctor and I wanted to make my mom proud, so I wanted to do something related to medicine," he said.

He also noted that while serving as a domestic policy adviser for former President George W. Bush, he was involved with the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration.

"Finding good mentors is invaluable in any work environment, but certainly in a legal environment. It's the best way to learn and to model your own style."

He also worked in the White House for former President George H.W. Bush and spent the years during Bill Clinton's presidency at Kirkland, where he worked on general litigation, particularly for General Motors.

"I just became totally fascinated by the life sciences space, the drug industry generally, but health care from a policy perspective," he said of the latter Bush years. "When I came back to private practice after leaving the White House, it was just an industry that I really gravitated to both because of the substance and because it's a heavily regulated industry and so it fit well with my skill set, having been both a regulatory lawyer in the White House and then on the policy side."

Lefkowitz said that life sciences work only makes up about half of his practice now, with the rest still being general litigation.

His advice for junior attorneys:

Lefkowitz said the best way to move forward in your career is to find a strong mentor.

"Try to identify people at the firm where you work or at the company where you work who will really take an interest in your career and mentor you," he said. "Finding good mentors is invaluable in any work environment, but certainly in a legal environment. It's the best way to learn and to model your own style."

He also encouraged attorneys to take on as many opportunities as they can.

"Just say yes. Say yes to opportunities," Lefkowitz said. "The more opportunities you get, the more experience you'll have, and the more experience and responsibility you'll get. Say yes to senior lawyers who are themselves really busy — you'll get tremendous responsibilities and experience really early."



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