

Litigation and Enforcement Highlights – November 2018

The theme last month in litigation and enforcement action seems to be drug pricing. As the national debate surrounding rising prescription drug prices continues to heat up, we are seeing increasing legal action targeting the cause of such price hikes at the private, state, and federal levels. In our highlights this month, we look at how drug manufacturers and pharmacy benefit managers are coming under fire for their drug pricing practices, and how two states have turned to the Supreme Court to salvage their laws designed to rein in rising drug prices.

Soaring Prices of Insulin Under Fire from Multiple Fronts

Minnesota's attorney general took the public outcry against high drug prices to court last month, accusing Sanofi, Eli Lilly, and Novo Nordisk, the three largest manufacturers of insulin, of price gouging.[1] The lawsuit, filed in New Jersey district court, alleges that the drugmakers fraudulently set an artificially high sticker or "list" price for the diabetes drug, and then negotiate lower "net" prices by paying rebates and discounts to pharmacy benefit managers (PBMs). This practice harms people who don't have insurance or have high deductible health plans, as they must pay the higher sticker price out of pocket. Recent insulin price hikes triggered consumer outrage and state investigations of insulin pricing. The complaint contends that the defendants have tripled insulin's list price over the past 16 years and cites the example of Sanofi's insulin price, which increased from \$99.35 in 2010 to \$269.54 in 2018.

Separately, the American Medical Association (AMA) is urging the

Federal Trade Commission (FTC) to monitor insulin pricing and market competition, and to recommend further enforcement action as necessary. In a [letter](#) to FTC Chairman Joseph Simons, the AMA contends that “anticompetitive behavior by manufacturers and pharmaceutical benefit managers,” instead of “actual costs of research, development, commercialization, or production,” may have contributed to increases in insulin prices.

Judge Denies Motion to Dismiss Suit Against PBMs Over EpiPen Pricing Scheme

In another case challenging the pricing of a common prescription drug, buyers of EpiPen, who sued PBMs over their pricing scheme, survived defendants’ motion to dismiss. The putative class action alleges that EpiPen manufacturer Mylan jacked up the drug’s price as a result of negotiations with defendant PBMs, including Express Scripts and CVS Health, and the defendants were able to pocket rebates or other payments, in breach of their fiduciary duty under the Employee Retirement Income Security Act (ERISA).[2] In denying the motion to dismiss, Minnesota federal judge Paul A. Magnuson [found](#) that Plaintiffs adequately alleged that the PBMs were ERISA fiduciaries. Specifically, they “plausibly alleged that Defendants’ demands for rebates and other payments caused Mylan to raise the price of EpiPens,” resulting in higher copayments for the insureds. In addition, the insureds sufficiently alleged that “[d]efendants control the amount they receive in rebates or other fees from Mylan and likewise exercise discretion over how much of that money is paid to the plans.” Given the fervent attention on drug prices driven by dramatic price hikes of commonly used drugs such as insulin and EpiPen, we can expect more litigation and enforcement actions from private, state and federal parties, which can hopefully act as a legal checkpoint, on top of

legislative attempts, to help rein in drug prices.

Maryland and Arkansas Seek Supreme Court Review of Drug Pricing Laws

On the legislative front, states are turning to the Supreme Court to save their state laws to control rising drug prices. As widely expected, Maryland's attorney general petitioned the Supreme Court to review the 4th Circuit's decision to strike down Maryland's law against price gouging of generic drugs. In April, the federal appeals court [held](#) the landmark 2017 law unconstitutional because it violated the dormant commerce clause and refused to grant a rehearing en banc. In the petition for certiorari filed last month, the Maryland AG argued that the 4th Circuit decision "prevent[s] Maryland and other states from reining in abusive prescription drug prices that harm their consumers and the public health."

Separately, Arkansas is also petitioning the Supreme Court to overturn a federal appeals court decision to strike down its drug pricing law. In June, the 8th Circuit Court of Appeals held that ERISA and Medicare Part D preempted Arkansas' Act 900, which requires disclosure of generic drug pricing and sets a floor on prices that PBMs can pay to pharmacies. Similar to Maryland, Arkansas argues that its law is a valid attempt to "curb abusive prescription drug reimbursement practices," in this case by the PBMs. As previously covered on The Source Blog, several other states are engaged in legal challenges of similar legislation to regulate PBMs. While the 8th Circuit struck down a similar law in Iowa,[3] a district court upheld North Dakota's law,[4] which is now on appeal to the 8th Circuit.

As federal courts around the country debate the legality of the wave of state legislation enacted to combat high drug prices, consideration by the Supreme Court will no doubt help direct the future of such legislative attempts, many of which have been deterred or on hold pending the legal challenges (see The Source's Spotlight on 2018 State Drug Legislation: Part 4 –Price Gouging Prohibitions). The Source will be sure to bring the latest development and analysis on our Blog.

That's all for this month's Litigation and Enforcement Highlights. Stay tuned for the latest developments in these cases and check back next month for more litigation and enforcement actions on [The Source Blog](#). In the meantime, be sure to check out the [Enforcement page](#) of The Source for timeline and geographic trends of federal, state, and private enforcement actions.

[1]Minnesota v. Sanofi-Aventis U.S. LLC, D.N.J., No. 18-cv-14999.

[2]In re EpiPen ERISA Litig., No. 0:17-cv-01884-PAM-HB.

[3]Pharm. Care Mgmt. Ass'n v. Gerhart, 852 F.3d 722, 63 EBC 1085 (8th Cir. 2017).

[4]Pharm. Care Mgmt. Ass'n v. Tufte, 2018 BL 319762, D.N.D., No. 1:17-cv-00141.