

Litigation and Enforcement Highlights – February 2020

The Source has been closely following legal challenges to state legislation that seek to promote competition and contain costs in healthcare services. In this month's Litigation and Enforcement Highlights, we roundup the latest developments in some of the pending cases as well as new lawsuits that have been filed to derail state efforts to address rising prescription drug costs.

Arkansas: Supreme Court Grants Review of PBM Law

In November 2019, the Source Blog covered the long [litigious history](#) of lawsuits filed against various pharmacy benefit manager (PBM) laws from states including Maine, Iowa, and Arkansas. Due to inconsistencies in the rulings of the circuit courts, the issue of federal preemption of the Employee Retirement Income Security Act (ERISA) is ripe for Supreme Court review. Since the 8th Circuit struck down Arkansas' 2015 law in 2018, which requires disclosure of generic drug pricing and sets a floor on prices that PBMs can pay for generic drugs, 32 states have [joined](#) Arkansas' petition urging Supreme Court review.

Last month, following recommendation by the [U.S. Solicitor General](#), the high court granted the [petition for certiorari](#) to hear the case. With intense scrutiny on PBM practices and skyrocketing drug prices, the Supreme Court review could not have come at a better time. Not only will this provide greater certainty for pending cases in North Dakota (currently pending in 8th Circuit) and Oklahoma (potentially headed to the 10th Circuit), as well as at least 38 states that regulate PBMs, it will also offer much needed guidance for all states attempting

to implement healthcare pricing legislation that may trigger federal preemption.

California: Challenge of Pay-for-Delay Law Heads to Appeals Court

In California, another type of state legislation to tackle drug pricing has been under attack from the pharmaceutical industry. In an effort to promote generic competition in the prescription drug market, California enacted [AB 824](#) in 2019, a first-of-its-kind legislation that bans reverse payment settlements of drug patent disputes in which brand name companies compensate generic drugmakers to delay its entry into the market. The law presumes any reverse payment or pay-for-delay deal to have anticompetitive effects under California's Cartwright Act and imposes fines of up to \$20 million per violation.

Shortly after Governor Newsom signed the bill, the Association of Affordable Medicines [filed a lawsuit](#) in November 2019,^[1] claiming that the law will have the “perverse” effect of actually delaying generic entry and alleges violation of due process, the dormant commerce clause, and supremacy clause, among others. On December 31, the District Court [rejected](#) the plaintiffs' motion for preliminary injunction to block the law, primarily due to the burden of proving the statute was unconstitutional before it went into effect because no harm has occurred. Specifically, Judge Troy Nunley wrote: “Because AB 824 has not been enacted, nor has any other similar law been enacted in another state, it is impossible to know if this law will have its intended effect... The court is not in a position to predict the future impacts of AB 824 before it is enacted and enforced.” As a result, the law was allowed to take effect on January 1, 2020.

This ruling is strikingly similar to the reasoning employed in

another drug legislation challenge in California, namely against SB 17, the controversial drug pricing transparency law. In that case, District Court Judge Morrison England Jr. initially [tossed the case](#) because the complaint only speculated harm and did not establish actual or immediate injury. However, the lawsuit was [allowed to proceed](#) after PhRMA [amended](#) the complaint and is now pending in the same district court that struck down the AB 824 lawsuit. In fact, Judge Nunley indicated in his opinion that “if the Attorney General were to enforce the terms against two out-of-state parties that entered into a settlement agreement outside of California, having nothing to do with California, such conduct would likely violate the Dormant Commerce Clause.” Giving the pharmaceutical industry hopes that the challenge might yet have legs.

On top of this, let’s not forget that the U.S. Supreme Court had reviewed such pay-for-delay arrangements in the 2013 federal enforcement case *FTC v. Actavis*, which ruled, contrary to the new California law, that reverse payment deals are not automatically presumed to be anticompetitive and must be shown on a case-by-case basis. Given the law’s departure from case precedent, it is not surprising that Plaintiffs have already [filed an appeal](#) to the 9th Circuit Court of Appeals, promising a long road ahead in legal challenges for this law.

Oregon: PhRMA Challenges A Pair of Drug Pricing Transparency Laws

In more efforts to thwart state legislation to encourage drug pricing transparency, PhRMA, the same trade group that challenged California’s [SB 17](#), has filed a similar lawsuit against two new Oregon laws that target the same issues. The first law, known as the Disclosure Law ([HB 4005](#)), was enacted in 2018 and requires notification and justification when drug list prices increase by at least 10% or a new medicine costs

more than \$670 a month. The second law, the Advance Notification Law ([HB 2658](#) from 2019), requires advance notice of price hikes that are at least 10% or \$10,000 more than the preceding year. Both laws have become effective and the [lawsuit filed](#) in Oregon district court alleges that these laws violate trade secret protection, the commerce clause, and free speech. This case will now proceed in parallel with the SB 17 litigation in California, which it closely mirrors.

All of these cases will be on our radar for new developments as the courts decide on the various federal preemption issues and set boundaries of state power to legislate and regulate healthcare competition and prices. Stay tuned to future Litigation and Enforcement Highlights!

[\[1\]](#) Ass'n for Accessible Medicines v. Becerra, E.D. Cal., No. 19-cv-2281, 11/12/19.