

Litigation and Enforcement Highlights - September 2018

In this month's Litigation and Enforcement Highlights, we recap two small but meaningful wins in courts for state legislation aimed at controlling rising drug prices. We also take a peek at the newest developments of two potential mega mergers and the legal challenge against the Affordable Care Act, both of which could change the landscape of the healthcare industry.

Judge Boots Challenge Against California's Transparency Law on Technicality

In the latest development of the legal challenge against California's recently passed SB 17, the U.S. District Court for the Eastern District of California dismissed the lawsuit, ruling that Pharmaceutical Research and Manufacturers of America (PhRMA) failed to prove its legal standing and gave plaintiffs 30 days to refile and satisfy standing requirements. SB 17 is a hotly debated drug pricing transparency law that was enacted in October 2017, and requires drug makers to provide 60 days advanced notice and reason for price hikes above a certain threshold. PhRMA, the pharmaceutical industry's main lobbying group, challenged the law on constitutional grounds, alleging the law violates the First Amendment and the Commerce Clause.

U.S. District Judge Morrison England Jr. [held](#) that PhRMA, in its complaint, only speculates harm to the pharmaceutical companies it represents. The complaint does not establish that any of its members have been injured or will immediately be injured by the law, and therefore does not have standing to sue. Specifically, "in the Complaint, PhRMA... does not state that one of its members actually plans to make a pricing change that will force it to give 60-days' notice and trigger reporting or that one of its members will affirmatively refrain from increasing a drug price in order to avoid triggering the requirements."[\[1\]](#) The Court allowed PhRMA to amend its complaint to satisfy the standing requirement by showing that potential harm to drug makers falls "outside the realm of conjecture."

As the trade group is expected to amend its complaint, keeping the lawsuit alive, The Source will closely follow this case for further developments. For now, do not miss The Source's Katie Gudiksen and Jaime King's commentary "[California's Drug Transparency Law: Navigating The Boundaries Of State Authority On Drug Pricing](#)" in the September issue of Health Affairs for an in depth analysis of SB 17 and insights into whether it could withstand legal challenges.

North Dakota Drug Pricing Law Survives Federal Preemption Challenge

In other encouraging news for state efforts to control rising drug prices, the U.S. District Court of North Dakota upheld a 2017 North Dakota law against a legal challenge led by the Pharmaceutical Care Management Association (PCMA), a trade association representing pharmacy benefit managers (PBMs).^[2] The law in question regulates PBM reimbursement to pharmacies for prescription drugs and how much PBMs profit from such practice. Specifically, it requires disclosures of drug pricing and keeping the reimbursement rate above certain levels. As The Source highlighted in the July edition of Litigation and Enforcement Highlights, PCMA has successfully argued in lawsuits against similar laws in Arkansas and Iowa, that federal law preempts such state regulation of drug prices.

PCMA argues again here that the North Dakota law is barred by federal law, including the Employee Retirement Income Security Act (ERISA) and Medicare Part D. However, unlike the 8th Circuit ruling against Iowa's law^[3] and most recently Arkansas' law^[4], Judge Daniel L. Hovland [ruled](#) that North Dakota's law does not implicitly include ERISA plans. In addition, the court rejected the argument of Medicare Part D preemption, except the requirement for PBMs to disclose information to plan sponsors, such as the amount of rebates and amount paid to the pharmacy, as it overlaps with the federal disclosure requirement, which requires the same disclosures. Nonetheless, this ruling is a turn against the recent tide of federal preemption of state efforts to regulate drug prices. Stay tuned for more decisions that shed light on the boundaries of state regulation.

Mega Vertical Mergers Expected to Go Through

In healthcare consolidation news, two mega mergers on the horizon - Cigna-Express Scripts and CVS-Aetna - appear to be on their way to obtaining federal regulatory approval from the Department of Justice (DOJ), according to recent report by the Wall Street Journal.[\[5\]](#) For Cigna-Express Scripts, the proposed merger received approval from 14 out of 29 required states and received shareholder endorsement from both companies, despite challenge by investor Carl Icahn.[\[6\]](#) In the case of CVS-Aetna, approval may be conditional on the companies divesting or selling its assets in the Medicare Part D market to alleviate market concentration concerns raised by consumer advocacy groups as well as the American Medical Association and California Insurance commissioner.

If the deals do indeed go through, it would confirm speculation that DOJ's loss in the AT&T-Time Warner case, a vertical integration, would encourage and boost the odds of regulatory approval for other vertical mergers. The Source previously [highlighted](#) implications of that merger for both Cigna-Express Scripts and CVS-Aetna. The ultimate outcome of these two proposed mergers could not only reshape the insurance and pharmacy industries, but also signal the Trump administration's approach to antitrust regulation and establish precedents for other major mergers, particularly vertical integration, in healthcare markets.

Fate of the Affordable Care Act Up for Debate in Texas Court

Last but not least, a lawsuit filed in federal court in the Northern District of Texas seeking to overturn the Affordable Care Act (ACA)[\[7\]](#) is poised to have significant impact on healthcare markets and the entire healthcare landscape. The proponents, 18 GOP attorneys general and two GOP governors, argue that when the Trump administration eliminated the tax penalty for the ACA's individual mandate as part of last year's tax bill, it rendered the entire ACA unconstitutional. They argue that because the Supreme Court's [validation](#) of the ACA's constitutionality in 2012 "rested solely on the flimsy support of Congress' authority to tax,"[\[8\]](#) now that the tax penalty is eliminated, the entire law is unconstitutional and invalid. While the current administration is technically the defendant in this case, the Trump

administration has indicated that it will not defend some parts of the law, including pre-existing condition protections. U.S. District Judge Reed O'Connor heard oral arguments in a three-hour hearing on September 5, 2018 and said he will issue a quick decision. Should the plaintiffs prevail in this case, it will likely make its way to the Supreme Court. With all the legal disputes surrounding the ACA making headlines, here is [quick guide](#) from the Los Angeles Times to help you keep track of all the major cases that could impact the healthcare industry.

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] Pharm. Research and Mfrs. of Am. v. Brown, et al., E.D. Cal., No. 17-cv-2573, 8/30/18.

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

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

[4] Pharmaceutical Care Management v. Rutledge, 2018 BL 202886, 8th Cir., No. 17-1609, 17-1629.

[5] Brent Kendall et al., *Justice Department Nearing Antitrust Approval of Health Mergers Combining CVS-Aetna, Cigna-Express Scripts*, Wall Street Journal (Sept. 5, 2018).

[6] Bruce Japsen, *Cigna: 14 Of 29 States Have Approved Express Scripts Deal*, Forbes (Aug. 29, 2018).

[7] Texas et al v. United States of America et al, 4:18-cv-00167

[8] Ken Paxton, *AG Paxton and Wisconsin AG File 20-State Lawsuit to End the Grip of Obamacare on Texas and the Nation*, February 26, 2018. Available here: <https://www.texasattorneygeneral.gov/news/releases/ag-paxton-and-wisconsin-ag-file-20-state-lawsuit-end-grip-obamacare-texas-and-nation>