

Litigation and Enforcement Highlights - July 2018

June has been a busy month in terms of healthcare litigation and enforcement action. In this issue, we highlight 1) implications of the AT&T-Time Warner merger for vertical mergers in healthcare, 2) FTC's big win in a pharmaceutical pay-for-delay case, and 3) constitutional challenges against state drug pricing laws.

AT&T-Time Warner Merger Encourages Healthcare Vertical Mergers but May Mean Little

Last month, a federal court approved AT&T and Time Warner's \$85 billion merger without condition, setting off a wave of speculation on how the decision could impact pending healthcare mergers. In a major setback for the Department of Justice (DOJ), Judge Richard J. Leon of the U.S. District Court for the District of Columbia found that the government had failed to prove the merger would lead to fewer choices and higher prices for consumers.[1] As a "vertical integration" where two companies operate in the same industry but do not produce competing products, AT&T and Time Warner's approved merger confirms the conventional belief that vertical mergers do not pose the same antitrust threats as horizontal ones between competing companies, and thus face less antitrust scrutiny.

Many expect this merger to influence how the DOJ reviews several vertical mergers in healthcare, including CVS-Aetna and Cigna-Express Scripts. The DOJ has requested additional information from all four companies. While this decision may boost the odds for these pending mergers, critics are warning, "not so fast." Antitrust experts caution that because vertical mergers can be much more complicated than a horizontal merger, they are likely evaluated on a case-by-case basis given the facts presented. In an op-ed for The Commonwealth Fund, David Blumenthal noted that Judge Leon's [ruling](#) relied heavily on the DOJ's failure to supply *sufficient facts* that prove the merger would harm consumers. As "the facts about vertical integration in health care are obscure... and likely to vary enormously

according to the details of the merger and from market to market,”[2] much uncertainty remains as to the outcome of these mergers.

In the case of CVS-Aetna, just a week after the AT&T-Time Warner decision, antitrust proponents scrutinized and attacked the proposed merger at a hearing before the California Department of Insurance. The panel of expert witnesses that testified against the merger included the President of the American Medical Association (AMA) and Professor Tim Greaney of UC Hastings College of the Law. Read more about the hearing in The Source’s [report](#).

FTC Wins Largest Monetary Award in Pay-for-Delay Case Against AbbVie

Meanwhile, in pharmaceutical antitrust enforcement, the Federal Trade Commission (FTC) scored a big win in the pay-for-delay case filed in 2014 against drug manufacturer AbbVie.[3] A federal judge in Philadelphia found that AbbVie illegally delayed generic versions of its testosterone replacement drug AndroGel from entering the market and ordered the payment of \$448 million in illegal profits to consumers.[4] Brand-name drug makers commonly use pay-for-delay, a practice in which they pay a generic competitor to delay releasing a cheaper version of its product in exchange for resolving patent lawsuits. In this case, AbbVie and its partner filed baseless patent infringement lawsuits against generic manufacturer Teva Pharmaceutical and Perrigo Company, which were then settled as part of a deal to delay the release of their generic drugs. U.S. District Court Judge Harvey Bartle III [wrote](#) in his opinion, “Defendants possessed monopoly power and illegally and willfully maintained that monopoly power through the filing of sham litigation. This sham litigation delayed the entry of much less expensive competitive generic products” into the market.[5]

This decision could set an important precedent for federal crackdown of major pharmaceutical companies’ efforts to block competition from cheaper generic versions of their drugs. Just last month, the FTC suffered an unexpected loss in the pay-for-delay case against Impax, when an administrative law judge dismissed the Commission’s antitrust claims. The FTC has already filed a notice to appeal, which is expected to happen in August. Follow federal enforcement against this

pharmaceutical anticompetitive practice as The Source continues to track additional pay-for-delay cases.

Enforcement of State Drug Pricing Laws Faces Federal Preemption

As rising drug prices continue to capture the nation's attention, a growing wave of states have enacted laws to promote transparency in the pharmaceutical industry and to contain drug prices. However, the states are also beginning to face legal challenges in the form of federal preemption. In [April](#), the 4th Circuit held that Maryland's price gouging law is unconstitutional because it violates the dormant commerce clause. Last month, two additional cases further demonstrate that state efforts must circumvent various forms of federal preemption to achieve the goal of controlling prescription drug costs.

In the first case, two pharmaceutical trade groups, PhRMA and BIO, dropped their lawsuit over Nevada's [SB 359](#) upon modification of the law to alleviate constitutional concerns. Nevada's law, signed by Governor Brian Sandoval in 2017, requires drug manufacturers to report a range of pricing information for a list of essential diabetes drugs compiled by the state, including pricing history and costs, price hikes above inflation, and rebates paid to pharmacy benefit managers (PBMs). Plaintiffs sued the state claiming the law is unconstitutional and deprives drug makers of their right to protect trade secrets under the Fifth Amendment.[6] In a move that appears to be designed to address the constitutional challenges raised by the plaintiffs, Nevada's Department of Health and Human Services adopted a [trade secret option](#) that would allow pharmaceutical companies to keep certain drug pricing data confidential when they begin complying with the new transparency law, provided they explain why the information shouldn't be disclosed to the public. The law went in effect July 1 with the newly inserted trade secret provision, but enforcement actions by state officials will not begin until January 15, 2019.

Arkansas' drug pricing law also came up against federal preemption when the U.S. Court of Appeals for the Eighth Circuit [held](#) that both the Employee Retirement Income Security Act (ERISA) and Medicare Part D preempted Arkansas' [Act 900](#). [7]

Act 900 requires disclosure of generic drug pricing and sets a floor on prices that PBMs can pay to pharmacies. Pharmaceutical Care Management Association (PCMA), a trade association representing PBMs, brought the suit against the state in 2015. The district court found that ERISA preempted the law but Medicare Part D did not.[8] The 8th Circuit took it a step further by affirming the ERISA preemption and ruling in favor of PCMA on the Medicare Part D preemption as well.

These developments should shed light on other pending litigation against similar state laws, including California's [SB 17](#). The Source will continue to follow state efforts to rein in healthcare costs and ensuing legislative challenges.

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] United States v. AT&T Inc., 2018 BL 56141, 290 F. Supp. 3d 1, D.D.C., No. 17-2511.

[2] David Blumenthal, *AT&T, Time Warner, and the Future of Health Care*, The Commonwealth Fund, Jun. 21, 2018. Available at: <https://www.commonwealthfund.org/blog/2018/att-time-warner-and-future-health-care>.

[3] Federal Trade Commission v. AbbVie Inc. et al., 2:14-cv-05151-HB.

[4] Statement of FTC Chairman Joe Simons Regarding Federal Court Ruling in FTC v. AbbVie, Jun. 29, 2018. Available at: <https://www.ftc.gov/news-events/press-releases/2018/06/statement-ftc-chairman-joe-simons-regarding-federal-court-ruling>.

[5] Federal Trade Commission v. AbbVie Inc. et al. at 77

[6] PhRMA and BIO v. Sandoval, D. Nev., No. 2:17-cv-2315.

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

[8] Pharmaceutical Care Management v. Rutledge, E.D. Ark., No. 4:15-cv-00510-BSM.