

Litigation and Enforcement Highlights – October 2018

It's been an eventful month for healthcare litigation and enforcement action. Following [coverage](#) in last month's Litigation and Enforcement Highlights, we revisit and follow up with significant new developments in SB 17 litigation and the CVS-Aetna and Cigna-Express Scripts mergers. Additionally, we take a peek at another major healthcare merger on the horizon.

PhRMA Refiles Lawsuit Challenging California's SB 17

Last month on The Source blog, we reviewed the California federal court's [dismissal](#) of PhRMA's legal challenge against SB 17 on procedural grounds and noted that plaintiff will likely refile its complaint to keep the lawsuit alive. As expected, on September 28, PhRMA amended and refiled its complaint within the 30-day period granted by the federal judge.

The revived lawsuit is [amended](#) in two ways. First, the original complaint, PhRMA v. Brown, named Governor Jerry Brown, along with Robert David, in their official capacities as defendants. However, the court [held](#) in its dismissal in August that Governor Brown had only "general oversight" of the state's executive branch and no direct connection to the enforcement of SB 17, and must be dismissed as a party. The amended complaint therefore removed Brown as defendant and is retitled PhRMA v. David.

Second, in the original complaint filed on December 8, 2017, PhRMA did not allege sufficient facts to establish that any of its members have been injured by SB 17, which was enacted in 2017 but didn't go into effect until January 1, 2018. The

district court dismissed the suit holding that PhRMA lacked standing to sue because its members' potential harms were merely speculation and conjecture. Now more than nine months into official enforcement of the law, PhRMA has amended the complaint to include new information describing how alleged constitutional violations of the First Amendment and the Commerce Clause directly harm individual PhRMA member companies. For example, several of PhRMA's member companies have filed advance notices of price increases "in violation of their constitutional rights." Amended Complaint at 33, PhRMA v. David, No. 2:17-cv-02573 (E.D. Cal. Sept. 28, 2018).

Now that the legal challenge against SB 17 has cleared procedural hurdles, the court must rule on the merits of the constitutional arguments, which could have far-reaching implications for state regulation of pharmaceutical prices across the country. The action in this case has just begun. Stay tuned as The Source continues to track the latest developments in this important case.

Two Transformative Healthcare Mergers Pass Federal Antitrust Scrutiny

In September, we [previewed](#) the imminent approval of two proposed vertical healthcare mergers, CVS-Aetna and Cigna-Express Scripts. In less than a month following that development, both mergers have officially gained regulatory approval from the Department of Justice (DOJ), promising to reshape the healthcare industry. Health insurer Cigna's acquisition of pharmacy benefit manager (PBM) Express Scripts was the first to receive federal approval, following a six-month investigation by the antitrust division of the Justice Department. In reviewing the transaction, the DOJ concluded the Cigna-Express Scripts merger

is unlikely to result in harm to competition or consumers because “Cigna’s PBM business nationwide is small” and “at least two other large PBM companies and several smaller PBM companies will remain in the market post-merger.”[1]

The swift approval of Cigna-Express Scripts also cleared the way for the pending \$69 billion merger of CVS and Aetna, as DOJ gave its final approval last week, contingent upon Aetna’s divestiture of its Medicare Part D business. CVS’s proposed acquisition of Aetna faced strong opposition from many antitrust experts and consumer advocacy groups, and antitrust regulators agreed that the merger could cause “anticompetitive effects, including increased prices, inferior customer service, and decreased innovation,”because CVS and Aetna are major competitors in the sale of Medicare Part D prescription drug plans to individuals.[2] To alleviate Part D consolidation concerns, Aetna reached an agreement in late September to sell its Part D business to WellCare, paving the way for the final approval of the proposed merger. Both deals are still pending regulatory approval in several states, but the green light from federal antitrust regulators has helped them clear the biggest hurdle and state approval is expected to follow.

While head turning, the Justice Department’s decision to sign off on these two major deals did not come as a complete shock. As The Source previously highlighted, there was much speculation that [DOJ’s loss](#) in the AT&T-Time Warner case signals a clearer path for similar vertical consolidation deals. Some antitrust enforcers believe that in vertical consolidation, merger or acquisition of companies in the same industry but do not directly compete with each other, the potential harm to consumers is reduced as compared to horizontal ones, and often does not outweigh the possible benefits from the merger. Accordingly, federal antitrust regulators have not successfully blocked a vertical merger in decades. However, there is still

much debate among economists, legal experts, and business leaders as to the implications of these mergers.

Proponents of the deals promise the mergers will provide better coordinated care by bringing pharmacy and insurance services under one roof. With more efficiency and negotiating power, the new entities could theoretically generate savings that translate into lower costs for consumers. On the other hand, the consolidation could exacerbate market power problems in the PBM market, which is heavily concentrated. As Source Advisory Board member Professor [Tim Greaney](#) warned, more than 70% of the PBM market could be combined with three of the largest health insurers, and smaller insurers that operate “without an effective and well-functioning PBM provider partner... could be at a disadvantage.”[3] For now, the ultimate impact of these mergers remains unclear. What is clear is the shift in the healthcare landscape, where powerful health insurance companies and dominant pharmacy benefit managers are joining forces to transform healthcare, for better or for worse.

Major Massachusetts Hospital Merger Raises Antitrust Concerns

We’ve been following the proposed merger of Beth Israel Deaconess Medical Center and Lahey Health since our [inaugural issue](#) of Litigation and Enforcement Highlights in January, when the Massachusetts Health Policy Commission (HPC) began its review of the deal for its potential impact on healthcare costs and quality. Since then, the deal seemed to be on its way to approval when it received the green light from two other [state advisory panels](#), before final review by the HPC and the state attorney general. However, HPC has completed its review and released a final report last month that may threaten to put the brakes on this transaction.

In line with the [preliminary report](#) released in July, HPC's [final report](#) concluded that the proposed merger could increase total healthcare spending by \$171 million per year and create problems for healthcare access by low-income and minority patients. Beth Israel and Lahey had argued that because the merged entity would form the second-largest hospital system in Massachusetts, allowing it to compete with the state's largest provider network, Partners Healthcare, it would gain increased leverage to negotiate and lower prices. However, HPC believes the enhanced leverage would be used to demand higher prices from insurers and instead increase overall spending. The commission implores the Public Health Council, which gave its approval back in April, to reconsider its decision, and urges the attorney general, who has the final authority to approve or challenge the deal, to impose conditions and enforceable restrictions on the merger to mitigate effects of increased costs. As AG Maura Healy may be heeding this advice as previously [signaled](#), this merger agreement will likely require significant modifications in order to go through.

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] *Statement of the Department of Justice Antitrust Division on the Closing of Its Investigation of the Cigna–Express Scripts*

Merger, Sept. 17, 2018. Available at: <https://www.justice.gov/atr/closing-statement>.

[2] *Justice Department Requires CVS and Aetna to Divest Aetna's Medicare Individual Part D Prescription Drug Plan Business to Proceed With Merger*, Oct. 10, 2018. Available at: <https://www.justice.gov/opa/pr/justice-department-requires-cvs-and-aetna-divest-aetna-s-medicare-individual-part-d>.

[3] Rose Meltzer, *The Department of Justice approved Cigna's acquisition of Express Scripts. What now?* Fierce Healthcare, Sept. 19, 2018.