



CRA Insights: Life Sciences

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CRA's Life Sciences Litigation team provides periodic summaries of notable developments in litigation. In this *Insights*, we note an antitrust class action regarding "usual and customary" prices for drugs dispensed at pharmacies and a summary judgment ruling stating that a co-pay assistance program that included Medicare Part D beneficiaries violated the anti-kickback laws.

***Carl Washington et al. v. CVS Pharmacy Inc., Northern District of California,
No. 4:15-vc-19-03504***

On June 23, 2021 a federal jury in northern California unanimously cleared CVS Pharmacy, Inc. (CVS) of overcharge allegations made by multiple classes of insured prescription drug purchasers from six states.

Background

In a proposed class action initially filed in 2015, Plaintiffs alleged that CVS engaged in a "common fraudulent and deceptive pricing scheme" under which it overcharged customers with third-party health care plans for generic prescription drug purchases. Plaintiffs alleged that CVS caused customers with third-party health care plans to pay significantly more in co-payments than cash-paying customers for the same drugs by failing to accurately report its usual and customary (U&C) price. At issue was CVS's Health Savings Pass (HSP) program and whether its prices should count as U&C prices.

On September 5, 2017, the Court granted Plaintiffs' motion in part for class certification, certifying four of the six state classes, limited only to the pharmacy benefit manager (PBM) that adjudicated each class representative's claim. The Court also granted the Defendants' motion in part, excluding the Plaintiffs' damages expert's opinion that HSP prices are U&C. The Court entered judgment in favor of CVS on September 13, 2017, and Plaintiffs appealed. The Ninth Circuit reversed the Court's rulings and remanded the action for further proceedings. On August 23, 2019, the Court certified the class without its initial limitation.

Verdict

On June 23, 2021, a federal jury in the Northern District of California unanimously found that CVS did not violate the respective state consumer protection acts and cleared CVS of overcharge allegations. The jury verdict was consistent with current and former PBMs' testimony that their contracts did not require CVS to report HSP prices as U&C prices.¹

Pfizer Inc. v. United States Department of Health and Human Services, et al., Southern District of New York, No. 120-cv-04920

A Southern District of New York judge ruled that Pfizer's co-pay assistance program that included Medicare Part D beneficiaries violated the anti-kickback laws.

Background

In June 2020, Pfizer sought declaratory judgment against the US Department of Health and Human Services (HHS), its Secretary, the Office of the Inspector General (OIG), the Principal Deputy Inspector General, and a senior official in OIG in an effort to provide Medicare beneficiaries, who are unable to afford co-pays under their Part D prescription drug benefit, financial assistance for two medications, Vyndamax and Vyndaqel, to treat a heart condition called transthyretin amyloid cardiomyopathy. Pfizer claimed that otherwise government restrictions and OIG actions would define their proposed co-pay assistance programs for Medicare Part D beneficiaries as unlawful kickbacks.

Verdict

On September 30, 2021, the Court denied Pfizer's motion for summary judgment, stating that "the law is clear that absent an express carve-out, the Anti-Kickback Statute prohibits any remuneration intended to induce someone to purchase or receive a drug or medical service. No independent corrupt intent or direct quid pro quo is necessary."

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¹ Atkins, Dorothy, "California Jury Clears CVS in \$121M Drug Overcharge Trial," *Law360*, June 23, 2021, <https://www.law360.com/articles/1397060/calif-jury-clears-cvs-in-121m-drug-overcharge-trial>.

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