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Ninth Circuit Holds FCA Claims Related to 340B Program May Proceed

On March 17, 2026, the U.S. Court of Appeals for the Ninth Circuit issued a decision addressing how the False Claims Act (FCA) may apply to alleged 340B Drug Pricing Program overcharges. In *United States ex rel. Adventist Health System of West v. AbbVie Inc.*, the court reversed dismissal of a qui tam action brought by a covered entity against several drug manufacturers, holding, at the pleading stage, that the relator stated viable FCA claims tied to alleged 340B ceiling-price noncompliance.

Background

The federal 340B Drug Pricing Program requires participating manufacturers to offer covered entities drugs at or below a statutory “ceiling price.” The relator, Adventist Health System of West (Adventist), alleged that four drug manufacturers knowingly charged covered entities more than statutorily permitted, particularly in circumstances where Adventist contends the 340B pricing formula would yield a ceiling price at or below zero, requiring a \$0.01 “penny price.”

Adventist did **not** seek to recover its own alleged overcharges as a purchaser. Instead, it alleged that the manufacturers’ pricing practices **harmed the federal (and state) governments** by increasing amounts paid under government healthcare programs and by other government purchasers, including:

Medicaid payments allegedly reflect inflated drug acquisition costs.

Medicare cost-based reimbursements to critical access hospitals.

Direct purchases by government-funded prisons and clinics.

The United States' Amicus Curiae Filing

The United States filed an amicus brief urging reversal of the district court's dismissal. The government argued that FCA claims alleging financial harm to the United States are not foreclosed simply because the 340B statute does not provide a private right of action for covered entities and because 340B has an administrative enforcement framework. The government also emphasized the FCA's role as a principal anti-fraud tool and stated it took no position on the ultimate merits of the relator's claims.

What the Ninth Circuit Held

The Ninth Circuit concluded that Adventist plausibly alleged FCA claims and that neither the 340B statute nor the Supreme Court's decision in *Astra USA, Inc. v. Santa Clara County* categorically bars such a suit.

In particular, the court held, again at the pleading stage, that:

FCA claims are “free-standing and independent” and are not automatically barred merely because covered entities lack a private right to sue to enforce 340B requirements directly.

Adventist was not, “in essence,” bringing a private enforcement action under 340B, but rather alleging false claims that caused government overpayment.

Adventist plausibly alleged falsity based on the statutory pricing framework and related guidance addressing penny pricing when the ceiling price calculation yields a zero or negative result.

The Ninth Circuit also noted that, absent a clear statutory carve-out, courts generally do not create program-specific exceptions to the FCA.

Practical Implications

This decision may affect 340B Program participants broadly (manufacturers, covered entities, and contract pharmacies) because it recognizes a pathway (at least in the Ninth Circuit and at the pleadings stage) for alleged 340B issues to be litigated as FCA claims where an alleged overcharge is tied to government payment.

Program mechanics may matter more. The decision underscores that participants' choices in operationalizing and documenting 340B arrangements (including penny pricing scenarios) may become central in disputes that allege downstream government overpayment.

Increased litigation risk. Even when the alleged unlawful pricing conduct is attributed to one group of actors, FCA cases can lead to broader document demands, data analyses, and scrutiny across the drug distribution and reimbursement chain (including pricing, charge/reimbursement practices, and communications among participants).

Jurisdictional and fact-specific limits remain. The Ninth Circuit's decision resolves only threshold pleading issues. Later stages may turn on materiality, scienter, damages, and program-specific reimbursement facts.

Conclusion

This lawsuit remains at an early stage and returns to the district court for further proceedings on remand. Still, the Ninth Circuit's recognition of a viable FCA theory tied to alleged 340B ceiling price noncompliance could be significant both in this litigation and in other scenarios where pricing practices are alleged to affect government payment.

Contact us

If you have questions regarding the 340B Program or how this decision may affect your organization, please contact Robert Hess, Renee Zerbonia, or your Husch Blackwell attorney.