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Ninth Circuit Permits 340B Program Enforcement Under the FCA

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Drug manufacturers participating in the Section 340B Drug Pricing Program now face a significant new litigation risk under the False Claims Act ("FCA"). In a recent decision, Adventist Health System v. AbbVie, the Ninth Circuit reversed a district court to hold that a covered entity can pursue an FCA *qui tam* action premised on 340B overcharging even though Section 340B itself provides no private right of action. For hospitals, health systems, and other 340B-participating entities, the ruling deserves careful attention.

Background: The 340B Program and Astra USA v. Santa Clara County

The 340B Program, created in 1992, requires drug manufacturers that participate in Medicaid to sell drugs to qualifying covered entities, such as safety-net hospitals, federally qualified health centers, and similar facilities, at ceiling prices set by a statutory formula. Covered entities use the discounted acquisition costs to stretch limited resources for low-income and uninsured patients.

For years, the principal legal obstacle to covered entities pursuing overcharge claims has been *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 113 (2011). The Supreme Court held that Section 340B suits by covered entities to enforce manufacturers' Pharmaceutical Pricing Agreements are "in essence" suits to enforce the statute itself, which are barred because the statute does not create a private right of action. If a covered entity believed it was overcharged, the exclusive remedy was Section 340B's Administrative Dispute Resolution process, administered by the Health Resources and Services Administration ("HRSA").

Covered entities have complained for years that the ADR process is slow, resource-intensive, and provides only direct remedies like overcharge reimbursement or PPA termination. Notably, the ADR process does not provide anywhere near the scope of damages and penalties available under the FCA, which allows treble damages and per-claim penalties.

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Adventist's Allegations

Adventist, a nonprofit operator of clinics and hospitals, alleged that AbbVie, AstraZeneca, Novartis, and Sanofi knowingly charged prices that violated 340B's ceiling price formula for many years. According to the *qui tam* complaint, all four manufacturers dropped the prices for several categories of drugs to $0.01, the default price when 340B's ceiling price formula results in a ceiling price of $0 under HRSA's penny pricing rule. Adventist contends that market forces could not explain the sudden uniformity of the decrease, but instead that the drop is explained by years of inappropriate price increases followed by belated correction.

Adventist brought suit as a *qui tam* relator on behalf of the federal and state governments, alleging that the inflated manufacturer prices caused Medicaid and Medicare to reimburse covered entities at fraudulently inflated rates, that critical access hospitals overbilled Medicare at 101% of costs, and that government-funded prisons and clinics paid unlawfully inflated prices.

The Ninth Circuit's Holding

The Court reversed the district court's dismissal on two independent grounds. First, the Court reasoned that the absence of a private right of action under Section 340B does not bar an FCA *qui tam* action. The Court ruled that the FCA provides its own independent right of action and creates a cause of action on behalf of the government. As a result, Adventist was not suing to vindicate its own interests as a covered entity. Rather, it was suing on behalf of the government. The Court analogized to an earlier decision holding that the absence of a private right of action under the Service Contract Act did not bar a relator from bringing FCA claims premised on violations of that Act. To the Court, what mattered was whether false claims were presented to the government, not whether the relator could independently enforce the underlying regulatory requirement.

Second, the Court explained that Adventist's claims are not "in essence" an attempt to enforce Section 340B in an end run on *Astra USA*. There, the plaintiff sought compensatory damages for breach of contract, relief that mirrored what the 340B ADR process provides. Here, Adventist seeks treble damages and civil penalties under the FCA for false claims submitted to government healthcare programs. The Court concluded this difference placed Adventist's claims in a different category, noting that Adventist's claims of an FCA violation required more because "the violation of a statute does not itself create a violation of the FCA."

The Court also rejected the defendants' arguments regarding a failure to allege falsity, holding that the plain text of the statutory ceiling price formula independently required penny pricing regardless of any regulation, and that HRSA's 2011 written guidance had formally adopted that interpretation years earlier.

What This Means Going Forward

For covered entities, the decision potentially opens a previously unavailable avenue to

pursue fraud losses the government sustained from 340B overcharging, which is beyond the losses recoverable through the ADR process. Covered entities sitting on pricing anomaly data, or on evidence of precipitous price decreases like those alleged here, may have a viable FCA theory to evaluate alongside the ADR route.

For drug manufacturers, the exposure calculus has changed materially, particularly in the Ninth Circuit. FCA liability means treble damages plus per-claim civil penalties, consequences that would be far steeper than ADR reimbursement. The FCA's statute of limitations and statue of repose, however, may limit the scope of potential liability based on Adventist's theory.

The decision highlights the importance of documentation around 340B ceiling price calculations and compliance histories. The Court permitted Adventist's pre-2019 claims to survive at the pleading stage based on the theory that the statutory formula was self-executing. What discovery reveals about how the defendant manufacturers calculated and what the defendants knew about ceiling prices in earlier years will likely be key to ultimate exposure.

The Ninth Circuit's ruling has no immediate effect outside the circuit, and it may well be contested further. But given the scale of the 340B program, which facilitated more than $80 billion in drug purchases in 2024 alone, and the relative novelty of FCA theory, the *Adventist* decision is a development that organizations and practitioners across the spectrum will monitor closely.