

## Negotiating False Claims Act (FCA) Cases for Pharmacies: Key Strategies for an Effective Defense

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Pharmacies play a critical role in the U.S. healthcare system, providing essential medications to patients and facilitating access to life-saving treatments. However, as healthcare spending continues to rise, pharmacies increasingly face scrutiny by the U.S. government for potential violations of the False Claims Act (FCA). The FCA is frequently leveraged to address concerns about false billing or misrepresentations of services.

Pharmacies can face FCA investigations for various reasons, ranging from billing discrepancies and regulatory non-compliance to improper relationships with healthcare providers or insurers. When navigating a False Claims Act case, it is essential to understand the various ways pharmacies may run afoul. Effective negotiation strategies can help mitigate liability, minimize penalties, and reduce the potential for reputational damage.

Wilentz, Goldman, & Spitzer, P.A. has experience negotiating on behalf of clients facing FCA claims. Below are examples of the types of claims our firm has experience in addressing and some examples of how we have properly challenged these claims.

### 1. DIR Fees

One of the most common issues pharmacies face in FCA investigations is the application of Direct and Indirect Remuneration (DIR) fees. DIR fees are rebates or price concessions imposed by Pharmacy Benefit Managers (PBMs) or insurers on pharmacies at the time, or in some cases, after a drug is dispensed.

In cases where pharmacies can demonstrate the amounts they paid in DIR fees during the audited period, a reduction from the alleged overpayment for DIR fees can often be negotiated.

### 2. Brand Name Drug Package Sizing

Another frequent issue in FCA cases is the discrepancy between the National Drug Code (NDC) used for billing purposes and the quantity of drugs dispensed. Pharmacies may bill for a 30-count bottle of a drug, but in practice, they might order or receive a 90-count bottle. Despite receiving the same reimbursement, this practice still appears to show as a “false claim.”

False claim cases such as these can be explained and the overpayment may be reduced. For example, if a pharmacy bills for Januvia 50mg 30ct yet orders Januvia 50mg 90ct, as long as the pharmacy has sufficient total inventory of Januvia 50mg, there should be no overpayment.

### 3. Drug Bioequivalence

Generic drugs can have numerous NDC numbers. Billing for one NDC yet dispensing another is an improper practice and can violate several state regulations. Still, depending on the facts of each case, this may not be a per se violation of the False Claims Act. It may be appropriate to defend such a claim on the grounds that the alleged overpayment was based on generic bioequivalence.

### 4. Expanding Inventory Windows

False Claims Act claims provide the pharmacy with an audit period. The investigating agency, typically the DOJ, reviews the inventory ordered during that period and compares it with the pharmacy's billing records during the same period. Unfortunately, this form of audit does not account for inventory the pharmacy may have had in stock before the audit period, which was subsequently billed and dispensed during the audit period.

Our Pharmacy Law Attorneys Angelo J. Cifaldi and Joseph Carlo have experience not only practicing pharmacy law but also working in pharmacies. Angelo is President and Managing Director at Wilentz, Goldman & Spitzer, P.A.; Co-Chair of the Mass Tort/Class Action and Cannabis Law Teams, and a licensed pharmacist. Joseph is an Associate at Wilentz, Goldman & Spitzer, P.A. and was previously employed as a pharmacy technician for nearly a decade. If your pharmacy faces a False Claims Act investigation, contact Angelo or Joseph.

### **Attorneys**

- Angelo J. Cifaldi
- Joseph Carlo

### **Practice**

- Pharmacy Law