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# Five Trends in False Claims Act Enforcement: Take Two

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In July 2015, we **posted** about the N.Y. Attorney General's False Claims Act (FCA) settlements with Trinity HomeCare and its related entities, and how the case provided insight into the future of FCA enforcement. We identified five key trends based on the settlements:

1. The FCA cases were based on *qui tams* and pursued by the State Attorney General after federal government declination.
2. The FCA cases were based on a narrow, single state or regional arrangement, as opposed to allegations of a national scheme or program.
3. One of the FCA cases was based on conduct about which Trinity had previously been warned.
4. The FCA cases were based on government billings for specialty drugs.
5. All parties to the arrangement were named as defendants in the *qui tams*.

Trinity was already under investigation by the N.Y. Attorney General's office for its billing of hemophilia drugs (the basis of the first 2015 settlement) when a second *qui tam* alleged that Trinity submitted false claims in connection with a specialty drug used to treat premature infants at risk for lung disease. That second *qui tam* led to the second settlement and now, almost 20 months later, has led to a new Complaint.

**2017 Complaint in Intervention**

On March 31, 2017, the N.Y. Attorney General filed a **Complaint in Intervention** in the second Trinity *qui tam,* naming as the defendant the manufacturer of the drug used to treat premature infants at risk for lung disease. The Complaint alleges that the manufacturer operated a kickback scheme with Trinity which led to the submission of false Medicaid claims for "an expensive brand name injectable drug for infants for which there is no generic substitute" and thus violated the federal and state FCAs.

The Complaint alleges that Trinity shared patient information with the manufacturer that led to the identification of babies who might benefit from receiving the expensive, injectable drug. The Complaint also alleges that the parties did not execute HIPAA Business Associate Agreements or otherwise document compliance with patient privacy laws. Trinity allegedly used patient information to generate prescriptions for the manufacturer's drug, and bill N.Y. Medicaid more than $7 million dollars.

FCA enforcement continues to evolve, especially in the wake of the June 2016 Supreme Court decision in ***United Health Services v. United States ex rel. Escobar.*** In many ways this new Complaint provides insight into existing and likely future trends in FCA Enforcement. Some of these trends are the same trends we identified in 2015 and some of the trends have evolved over the past year and a half.

**Five FCA Enforcement Trends**

1. ***FCA Cases Based on Billing Government Programs for Specialty Drugs***

As we stated in our 2015 post, specialty drugs are expensive and arrangements related to these drugs continue to be a focus of FCA enforcement. In its Complaint in Intervention, the N.Y. Attorney General repeatedly emphasizes that the pediatric drug at issue was expensive and there was no available generic or less costly alternative. The drug came in 50 mg and 100 mg vials, with some infants requiring multiple vials per month. The Complaint states that, on average, Medicaid reimbursed $1910.32 for the 100 mg vial.

The N.Y. Attorney General alleges that the arrangement between Trinity and the manufacturer was intended to increase sales of this drug, benefitting the manufacturer through increased sales and Trinity through increased Medicaid reimbursement.

While the Complaint describes the arrangement as "cynical and profitable," it is significant to us that unlike multiple other kickback cases for specialty drugs, there is no allegation in this case that infants did not need the drug, that Trinity provided unnecessary drugs, or that the arrangement resulted in any patient harm. Put another way, the claims at issue are not allegedly false because the infants did not need or benefit from the drug, the claims are allegedly false merely because of the alleged underlying kickback.

2. ***FCA Cases Focusing on Financial Arrangements***

To FCA practitioners, the June 2016 Supreme Court decision in *Escobar* changed the landscape of FCA enforcement based on regulatory compliance, necessitating the government (or a relator) to establish that compliance with the underlying regulation was material to the government decision to pay the claim. But the federal FCA, and most state FCAs, specifically provide that claims based on alleged kickbacks are actionable as FCA violations. Therefore, arguably, materiality is not at issue in a FCA case based on alleged kickbacks – the statute itself establishes materiality.

But the Trinity case is not a traditional kickback case where money changed hands between the parties to the alleged kickback. Instead, the alleged kickback was the business relationship between the parties that purportedly benefited both the manufacturer and Trinity, or as the N.Y. Attorney General termed it, the "cynical and profitable" arrangement.

According to the N.Y. Attorney General, the alleged remuneration at issue in the arrangement was (a) the "valuable" leads the manufacturer provided to Trinity regarding infants who might benefit from the specialty drug, and (b) the assistance the manufacturer provided to Trinity to obtain prescriptions for the drug, in the form of outreach to physicians and facilities, and identifying specific information about patients and their insurance.

3. ***FCA Cases Involving Alleged Distasteful Conduct Underlying or Facilitating the Financial Relationship***

In the Trinity case, the *qui tam* relator was a physician who alleged that Trinity billed Medicaid for the drug at issue for one child based on a prescription that listed her as the prescribing physician, but she did not prescribe the drug. That allegation is repeated in the Intervening Complaint against the manufacturer, although it is not alleged that the manufacturer participated in the creation of that prescription. Further, the Intervening Complaint alleges damages based on prescriptions filled for 600 children, and there is no allegation that the prescriptions for the 599 other children covered by Medicaid were unauthorized by the named prescribers.

Instead, through the Intervening Complaint, the N.Y. Attorney General focuses on the actions the manufacturer's representatives allegedly undertook to identify infants who might benefit from the drug–conduct repeatedly referred to as "aggressive" generation of "baby leads." And it is alleged that the manufacturer's representatives identified these "baby leads" by accessing patient records, including personal health information, without proper authorizations or paperwork establishing HIPAA compliance. Those "baby leads" were then allegedly passed on to Trinity to turn into referrals for the drug that Trinity would bill to, and be reimbursed by, Medicaid.

Had the N.Y. Attorney General alleged the violations of HIPAA rendered the claims false, the assertions would have been subject to the *Escobar* standard for implied certifications. Instead, the alleged HIPAA violations are used as aggravating or distasteful conduct used to facilitate the alleged "baby leads" that form the heart of the kickback allegation.

4. ***FCA Cases Pursued Despite Federal Declination***

The federal government initially delayed an intervention decision in the underlying Trinity *qui tam,* but according to a letter filed with the Court on the Trinity settlement, it did assist in the N.Y. Attorney General's investigation. According to that same letter, the federal government formally declined to intervene in the case on July 30, 2013, but monitored the case and consented to the N.Y. Attorney General's settlement with Trinity.

In our 2015 post on the Trinity settlement, we noted that in the olden days of FCA enforcement (approximately 8 years ago) it was unusual for an FCA case to proceed without federal government intervention. More and more frequently, however, a federal declination may be just the first stage of FCA litigation. When the federal government declines intervention in a Medicaid-based case, it may do so knowing the matter may be pursued by state Attorneys General. And it seems that every day we hear of another FCA case being pursued by relator's counsel after federal declination.

5. ***FCA Cases Pursued Against All Parties to the Alleged Improper Relationship***

In past FCA cases alleging kickbacks to increase pharmacy sales, government enforcement often targeted the deepest pockets – generally manufacturers who allegedly paid the kickbacks and thus "caused" the false claims to be submitted. Manufacturers would frequently argue that it takes two to make a kickback, and that these arrangements were demanded by the providers. However, the government often reached FCA settlements with the companies that allegedly paid the kickbacks and "caused" the false claims, with little in the way of consequences for the providers who allegedly received the kickbacks and the corresponding government reimbursement for the "false" claims at issue.

But now it appears that FCA cases involving pharmacy kickbacks are not finished until government enforcers have addressed all participants in the alleged kickback scheme. In the Trinity case, the N.Y. Attorney General receipt of a judgment for full reimbursement of its Medicaid program payments to Trinity for the drug at issue is apparently not a deterrent to pursuing a FCA case against the manufacturer of the drug for those same Medicaid payments.

As evidenced by the Trinity case and other recent enforcement efforts, manufacturer-provider arrangements relating to specialty drugs will continue to be subject to scrutiny. It is therefore important for the parties to such arrangements to properly document and structure the arrangement in light of recent enforcement and to ensure regulatory compliance in the operational implementation of the arrangement.

## Authors

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Theresa advises clients on all aspects of the pharmaceutical supply chain, including counseling industry stakeholders on a range of business, legal, transactional, and compliance matters. She provides clients with strategic counseling and creative business modeling that considers legal restrictions and regulatory risk in light of innovation and business goals.