

THE FCA & THE FDA
*Testing the Boundaries
of Qui Tam Law*

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FDA CLAIMS ARE BIG BUSINESS

In 2009, Pfizer paid a whopping \$2.3 billion to settle criminal & civil charges that it intentionally promoted a number of products off-label in violation of the FDCA, and paid illegal kickbacks to physicians to induce them to prescribe its products.

FDA CLAIMS ARE BIG BUSINESS

The deal included \$1 billion in civil penalties, making it the largest civil fraud case against any drug maker ever.

FDA CLAIMS ARE BIG BUSINESS

Pfizer's woes began in March 2003, when it terminated John Kopchinski, a senior sales representative in the territory of Broward County, Florida. Pfizer alleged it terminated him for participating in a theft of prescription drugs by his supervisor.

FDA CLAIMS ARE BIG BUSINESS

Kopchinski alleged he was the one who had reported his supervisor's misconduct to upper management, and that Pfizer had instead terminated him for investigating an illegal off-label promotion and kickbacks scheme involving the arthritis drug Bextra.

FDA CLAIMS ARE BIG BUSINESS

Kopchinski sued Pfizer a few months later under the *qui tam* provisions of the U.S. False Claims Act and several state false claims statutes, for causing providers to submit false claims to Medicare and Medicaid programs. He also brought a retaliatory discharge claim under the whistleblower protection provisions of the FCA.

FDA CLAIMS ARE BIG BUSINESS

Kopchinski's lawsuit, along with two other *qui tam* lawsuits involving several other Pfizer products, triggered a criminal investigation resulting in the felony conviction of a Pfizer subsidiary, criminal fines of \$1.2 billion, an expansive corporate integrity agreement, and the criminal convictions of two of its managers.

FDA CLAIMS ARE BIG BUSINESS

Kopchinski does not have to stand in the unemployment line any longer. His personal share of the settlement was over \$51 million.

HOW DID THE FCA BECOME A TOOL FOR FDA ENFORCEMENT?

- The first significant FCA case to bring together “off-label” marketing theories with the FCA was *U.S. ex rel. Franklin v. Parke Davis* (Mass.).
- *Qui tam* relator Franklin sued Parke-Davis (now a Pfizer subsidiary) for an alleged wide-spread off-label marketing and illegal kickbacks scheme involving the drug Neurontin in 1996.

HOW DID THE FCA BECOME A TOOL FOR FDA ENFORCEMENT?

- Like the more recent Bextra case, the Neurontin case also resulted in a criminal investigation against the company.
- In 2004, Parke-Davis agreed to pay \$430 million to settle the criminal and civil charges after the court denied its motions to dismiss the action.
- \$150 million of the total was paid to settle federal and state FCA claims.

HOW DID THE FCA BECOME A TOOL FOR FDA ENFORCEMENT?

- The FDCA forbids manufacturers from engaging in off-label promotion, but its enforcement rests solely with the federal government. The FDCA has no private enforcement provision.
- The FCA gives private citizens, *qui tam* relators, the right to sue on behalf of the federal government, but only in cases involving false or fraudulent claims to obtain federal funds. It does not create a private right of action to enforce every federal law.

So how did the court in *Franklin* conclude that off-label promotion of Neurontin could be a violation of the FCA?

HOW DID THE FCA BECOME A TOOL FOR FDA ENFORCEMENT?

- The court rejected the company's argument that its conduct was not fraudulent, but rather, a technical violation of off-label marketing restrictions. The court cited allegations that the promotions were not only off-label, but also untruthful.
- In a separate opinion, the court said no proof of false statements was required; all the relator had to prove was that the off-label promotion "caused" a false or fraudulent claim for reimbursement to be submitted.

HOW DID THE FCA BECOME A TOOL FOR FDA ENFORCEMENT?

- Parke-Davis argued that the conduct of physicians (who submit the claims for reimbursement and are responsible for their accuracy) breaks the chain of causation.
- The court rejected this argument, and held the submission of claims to government programs is a reasonably foreseeable consequence to manufacturers who promote off-label uses.
- The court thus concluded that manufacturers who promote products off-label “cause” claims for reimbursement of off-label uses to be submitted.

HOW DID THE FCA BECOME A TOOL FOR FDA ENFORCEMENT?

- Parke-Davis argued that since some off-label uses of Neurontin were covered by Medicaid, there was no fraud.
- The court rejected this argument, noting that most off-label uses of the drug were not covered, and further held that the off-label nature of the claims was material to government payers' reimbursement decisions.
- The court concluded that claims to government payers for reimbursement for the off-label uses promoted by Parke-Davis were fraudulent.

HOW DID THE FCA BECOME A TOOL FOR FDA ENFORCEMENT?

After *Franklin*, plaintiffs' theories in off-label FCA cases assert:

1. Drug & device companies that promote their products off-label can reasonably foresee that providers will submit claims for reimbursement to the Medicare & Medicaid programs; and
2. Providers' claims for payment from Medicare & Medicaid for drugs and devices used off-label are false or fraudulent.....ergo...

Manufacturers that promote off-label uses violate the FCA because they cause providers to submit false claims.

HOW DID THE FCA BECOME A TOOL FOR FDA ENFORCEMENT?

- **But... Reimbursement for devices and certain drugs is not always contingent on whether the use is off-label.**
- **If:**
 - The off-label use applies to a drug and is listed in CMS-approved compendia; or
 - The off-label use applies to a device, and no CMS national or local coverage decision limits reimbursement to FDA-approved indications;
 - AND there is no evidence of false statements;

The absence of any false or fraudulent claim could be a defense if no other basis for FCA liability (such as kickbacks) exists.

FCA CASES WITH FDA CLAIMS ARE ON THE RISE

- Since *Franklin*, nearly all of the off-label cases under the FCA in which the government has intervened have settled.
- Fear of exclusion from participation in the Medicare program (the corporate death penalty) likely drives these settlement decisions.

FCA CASES WITH FDA CLAIMS ARE ON THE RISE

In addition to the \$1 billion *Pfizer* settlement, the following off-label FCA settlements have been reported in just the last two years:

- Cephalon (Sept. 2008) - \$375 million
- Eli Lilly (Jan. 2009) - \$439 million
- Quest Diagnostics (Apr. 2009) - \$270 million
- AstraZeneca (Apr. 2010) - \$302 million
- Johnson & Johnson (Apr. 2010) - \$75 million
- Novartis (May 2010) \$72.5 million

FCA CASES WITH FDA CLAIMS ARE ON THE RISE

- Case law in this area continues to develop in cases where the government has not intervened, and cases that do not involve allegations of unlawful off-label promotion.
- For example, in the *Poteet* cases in the 6th Circuit and the District of Massachusetts (on appeal in the 1st Circuit), the courts dismissed the relator's claims under the prior public disclosure bar of the False Claims Act.
- *Poteet II* raised the question, whether a medical device company can be sued under the FCA for off-label violations, when CMS did not make reimbursement contingent on use within approved indications. The district court dismissed on public disclosure grounds without addressing this question.

THE FALSE CLAIMS ACT IS EVOLVING

In *Allison Engine Co. v. U.S. ex rel. Sanders* (June 2008), the Supreme Court curtailed liability under the FCA, which was triggered if the defendant:

1. Knowingly presented or caused to be presented to the government a false or fraudulent claim for payment or approval;
2. Knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the government; or
3. Conspired to defraud the government by getting a false or fraudulent claim paid.

The Court rejected the argument that Section 2 is implicated whenever a defendant's false statement to a third party results in payment using federal funds. Instead, the Court held the defendant must intend for the *government* to pay a false or fraudulent claim.

THE FALSE CLAIMS ACT IS EVOLVING

- **In May 2009, Congress expanded the FCA with the Fraud Enforcement & Recovery Act (FERA). Some of the changes are:**
 - Permits “reverse false claims” lawsuits: Providers may be sued for knowingly or recklessly retaining overpayments even in the absence of any false statement or claim.
 - Expands anti-retaliation protections for whistleblowers and explicitly allows DOJ lawyers to share information with them.
 - Tolls the statute of limitations when a *qui tam* complaint is filed (giving the government more time to investigate before it unseals a relator’s complaint)
 - Strengthens government power to issue civil investigative demands

THE FALSE CLAIMS ACT IS EVOLVING

- FERA also overturned *Allison Engine*.
- Section 2 is now triggered if the defendant:
 - Knowingly made, used, or caused to be made or used a false record or statement “material” to a false or fraudulent claim.
- “Material” is defined broadly. Essentially, the FCA is triggered if a false statement is made to any recipient of federal funds if the funds serve a government purpose (no requirement of intent to defraud the government).
- Congress tried to make FERA retroactive to the date of *Allison Engine*, by calling the amendments “clarifications”.
- Not likely to impact off-label cases significantly, since most have been allowed under FCA section 1 under the theory that off-label promotion causes providers to “present” false claims for payment to the government.

THE FALSE CLAIMS ACT IS EVOLVING

March 23, 2010, Congress expanded the FCA yet again, by enacting the Patient Protection & Affordable Care Act.

- A key defense to *qui tam* FCA suits is the “public disclosure bar.”
- Federal courts lack jurisdiction over whistleblower cases if the cases are “based on” a prior public disclosure, unless the whistleblower is an “original source”.
- The Affordable Care Act limits the definition of “public disclosure” to exclude information disclosed in *state* administrative or court proceedings; now only *federal* proceedings trigger the bar.
- The Affordable Care Act also expands the definition of “original source” to include relators who provide information to the government that is “independent of and materially adds to the publicly disclosed allegations or transactions.” (“Direct and independent knowledge” is no longer required.)
- These changes substantially limit important defenses in off-label and other cases where the government has not intervened.

THE FALSE CLAIMS ACT IS EVOLVING

- Not to be outdone, on March 30, 2010 (just 1 week after the Affordable Care Act was signed into law) the Supreme Court decided *Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*.
- *Graham County* resolved a circuit split as to whether the FCA's public disclosure bar can be triggered by disclosures made in *state* administrative proceedings.
- Applying the version of the FCA in effect before the Affordable Care Act amended it, the Court held that state proceedings *do* trigger the bar.
- In reaching its decision, the Court explicitly acknowledged the recent amendments, but held they were not retroactive to cases filed before the Act went into effect.
- Although the impact of the decision is limited to pending cases, it underscores what appears to be a growing tension between SCOTUS and Congress regarding how far the FCA should reach.

THE FALSE CLAIMS ACT IS EVOLVING

- The Supreme Court has pending a petition for certiorari in another public disclosure case, *Orthobiotech Products, L.P. v. U.S. ex rel. Duxbury*.
- The *Duxbury* petition seeks to resolve a circuit split as to whether a relator must present information to the government before filing suit only, or whether he must have presented the information before the facts were publicly disclosed.
- The petition also seeks to resolve a circuit split regarding the extent to which Rule 9(b) requires relators to plead specific false claims that were presented to the government.
- In May, the DOJ filed an amicus brief asking the Court to deny certiorari in *Duxbury* and address only the 9(b) issue by granting review in another pending case, *Hopper v. Solvay Pharmaceuticals*.
- *Hopper* is an 11th Circuit off-label FCA case, which the court dismissed under 9(b) because the relator had failed to point to any specific false claims for reimbursement submitted to the Medicare program.

THE FALSE CLAIMS ACT IS EVOLVING

What will happen next? All we know for certain is that the rapidly-changing law on the FCA will not be settled anytime soon.

Thank You

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