Pharmacy Law Brief: The Federal False Claims Act

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Pharmacy Law Brief: 
The Federal False Claims Act

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Question: I continually see mention of a federal law known as the Federal False Claims Act and, in association with that, read strange phrases and words such as “Quit Tam Action” and “Relator.” What is all that?

Response: The Federal False Claims Act (FCA) is a federal statute that creates potential criminal and civil liability for those who would defraud the federal government. This can apply either to individuals or to companies. The contemporary statute traces its origins to the Civil War when a variety of vendors sold defective or adulterated products to the federal government. Enactment of this statute during the administration of President Lincoln has resulted in this sometimes being referred to as the “Lincoln Law.” It can be found at 31 U.S.C. §3729.

One unusual feature of the statute is that it permits or authorizes individuals having no affiliation with the federal government to initiate legal actions on behalf of the government when they have knowledge of nefarious activities that might run afoul of the law. These people are sometimes referred to as “whistleblowers” and the resultant filings are called whistleblower lawsuits.

If the lawsuit is successful the person who filed the suit, referred to by the title “relator,” can be rewarded with 15-30 percent of the amount recovered. This provision authorizing an individual to file the lawsuit on behalf of the federal government and creating the entitlement to a portion of the amount recovered is called the qui tam provision. Those two words are a key portion of a long legal phrase in Latin that essentially means “he who sues in this matter for the king as well as for himself.”

Two of the key provisions in the False Claims Act serve to prohibit [1] knowingly presenting, or causing to be presented, a false claim for approval or payment, and [2] knowingly making, using or causing to be made or used, a false record or statement materials to a false or fraudulent claim. So either making the false claim or crafting documents to justify or support that false submission can run afoul of the law. It should be borne in mind that the statute mandates treble damages plus the court can impose additional penalties of between $5,500 and $11,000 per false claim.

There have been interesting shifts with the statute over time. During the Civil War the transgressions that first led to enactment of the statute primarily related to sales of material to the federal government for prosecuting the war. That focus on military-related purchase continued for quite some time. In fact, during World War II the statute was enacted to reduce the share of proceeds directed to the relator. Up through the 1980s the activities of defense contractors continued to be a principle focus of FCA-related activities. It is noteworthy, however, that by the late 1990s that focus had shifted to health care fraud. It is reported that false claims related to provision of health care goods and services now comprise a majority of cases filed under the statute.

The pharmaceutical industry, pharmacy chains and individual pharmacies have all come under scrutiny using the Federal False Claims Act. During recent years GlaxoSmithKline entered into a $750 million settlement with federal government under the False Claims Act and Ranbaxy Pharmaceuticals paid a $500 million settlement, both for allegedly releasing adulterated medications into interstate commerce.

The Department of Justice reports that the pharmaceutical industry was one of the largest contributors to settlements, with the predominant violation being alleged off-label promotional activities. Advent of Part D of Medicare with more direct, expanded federal payment for pharmaceuticals and pharmacy services has increased potential exposure in this area.
Between 2009 and 2012 the federal government recovered $9.5 billion under this statute. In FY 2013 alone the U.S. Department of Justice recovered $3.8 billion in civil settlements and judgments under the FCA. Of that total, $2.9 billion was recovered through *qui tam* actions. There were 752 *qui tam* actions filed during FY 2013, over 100 more than during the previous year.