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The 2009 False Claims Act Amendments and Implications for the Pharmaceutical and Medical Device Industry

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Objectives

- Understand the implications of recent changes to the Federal False Claims Act ("FCA") by the Federal Economic Recovery Act of 2009 ("FERA") on how FCA cases are investigated
- Analyze how these changes are consistent with pre-FERA prosecution trends
- Consider the effect of these changes on off-label compliance programs

The FCA

- Civil War-era statute originally passed to combat military contractor fraud
- Broadly prohibits knowingly presenting, or causing to be presented, a false or fraudulent claim for payment and other similar acts
- Allows private plaintiffs (known as “relators”) to bring actions on behalf of the government (*qui tam* provision)
- Analogous laws in a majority of states

The FCA (cont.)

- Prior to FERA, off-label promotion would implicate the FCA if a manufacturer:
  - knowingly presented, or caused to be presented, to an officer or employee of the US Government or a member of the Armed Forces a false or fraudulent claim for payment or approval
  - 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
  - conspired to defraud the Government by getting a false or fraudulent claim paid

The FCA (cont.)

- Modern approach to application of FCA to off-label cases based on Judge Saris' opinion in *ex rel. Franklin v. Parke-Davis* (D.Mass.)
  - Relator Franklin alleged evidence of a wide-spread off-label marketing scheme for Neurontin and Accupril
  - Government did not intervene right away – parent company Warner-Lambert filed a Motion to Dismiss in 2001 and 2003
  - Once the Government intervened, the case settled out of court in May 2004 for $430 million to settle criminal and civil charges in 2004
  - $150 million of the total was paid to settle allegations of Federal and State FCA violations

The FCA (cont.)

- Highlights of the Parke-Davis case opinions:
  - Evidence of off-label marketing alone is not sufficient to implicate the FCA and satisfy Fed. Rule. Civ. P. 9(b)
  - Physicians do not break the chain of causation between manufacturer and Government payor
  - Submission of a claim to a Government payor is a foreseeable consequence by a pharmaceutical manufacturer
  - Off-label nature of the claim is material to Government payors because not all off-label claims are reimbursed

The FCA After *Parke-Davis*

- The Government's theory of enforcement under the FCA:
  - 31 U.S.C. §§ 3729(a)(1) & (a)(2) (2008) are implicated where there is evidence that a manufacturer knowingly disseminated off-label promotional information regarding uses for which doctors would write prescriptions which were then submitted to Medicaid, Medicare, and other Federal Healthcare Programs

The FCA After *Parke-Davis* (cont.)

- Since the Parke-Davis case, every off-label case in which the Government has intervened has gone to settlement
  - The fear of exclusion from participation in Federal Healthcare Programs will likely continue to drive manufacturers to settlement
- Judge Saris' has been followed, though it remains controversial
- Rule 9(b) has been used by manufacturers to successfully dismiss or slow down a small number of cases where the Government has not intervened

The FCA After *Parke-Davis* (cont.)

- In 2008, DOJ reported securing over $1.34 billion in recoveries under the FCA
  - Of the total, more than $1.12 billion came from healthcare cases
- Since Fall of 2008, just four off-label FCA cases have represented over $2 billion in Federal and State recoveries:
  - Cephalon (Sept. 2008) – $375 million
  - Eli Lilly (Jan. 2009) – $439 million
  - Quest Diagnostics (Apr. 2009) – $270 million
  - Pfizer (Sept. 2009) – $1 billion

FERA

- FERA passed to combat corporate and mortgage fraud
- Effective May 20, 2009
- FERA § 4: “Clarifications to the False Claims Act to Reflect the Original Intent of the Law”
- Section 4 attempts to harmonize the FCA with current prosecutorial practice, controversial case law, and broad political goal of combating fraud

FERA (cont.)

- With a few notable exceptions, post-FERA off-label cases will “feel” the same as pre-FERA ones
- Number of cases will likely increase due to
  - Political pressure to cut healthcare costs and curb fraud and abuse at Federal and State level
  - Increased resources to investigating authorities
  - Enhanced statutory basis for cooperation among relators and government authorities

What Hasn't Changed?

- Penalties for violations continue to include treble damages and $5,500 - $11,000 per claim plus forfeiture of the claims
  - Losing defendants will continue to pay costs and attorneys fees
- Cooperation by defendant will continue to be a mitigating factor
- Government intervention in off-label will continue to result in settlement

What Hasn't Changed? (cont.)

- A defendant company will continue to be liable if, through its agents, it:
  - knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval
    - 31 U.S.C. § 3729(a)(1)(A) (previously § 3729(a)(1))
  - knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim
    - 31 U.S.C. § 3729(a)(1)(B) (previously § 3729(a)(2))
  - conspires to commit either of the aforementioned violations
    - 31 U.S.C. § 3729(a)(1)(C) (previously § 3729(a)(3))

What Hasn't Changed? (cont.)

- Prosecutors are likely to continue to take the position that dissemination of off-label information outside the boundaries of bona fide scientific exchange or FDA guidance is per se misleading
- Further, they will likely continue to rely on Judge Saris' interpretation of the FCA to conclude that such use of off-label information causes physicians to submit claims for payment by public payors (Medicaid, DoD, etc.) which satisfies the causation and materiality requirements of 31 U.S.C. §§ 3729(a)(1)(A) & (1)(B)

What Has Changed?

- Five major changes that will affect off-label FCA cases:
  - "Materiality" now defined broadly
  - "Presentment" requirement modified
  - Statute of limitations for Government's intervening filings now relates back to the filing date of the relator's complaint
  - Statutory basis for greater cooperation among relators, states and federal authorities, and prosecutors
  - Broader Civil Investigative Demand ("CID") provisions

What Has Changed? (cont.)

- Broad definition of "materiality"
  - Prior to FERA, courts held that plaintiffs had to show that the alleged falsehood was "material" for an action under the FCA to lie under 31 U.S.C. §§ 3729(a)(1) & (a)(2) (2008)
  - After FERA, materiality explicitly added to § 3729(a)(1)(B) claims
  - Defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property" 31 U.S.C. § 3729(b)(4)
  - Unlikely to change off-label cases brought under either (a)(1)(A) or (a)(1)(B) as *Parke-Davis* held that whether a promoted use is on- or off-label is material to Government payors under the statutes and regulations governing reimbursement decision-making

What Has Changed? (cont.)

- Congress modified the FCA's presentment language to partly "overturn" *Allison Engine* (S.Ct. 2008), *Custer Battles* (E.D. Va. 2005), and *Totten* (D.C. Cir. 2004)
  - These three decisions suggested that claims presented to subcontractors and certain Government contractors may be outside the purview of the FCA
  - Congress was concerned that these cases raised the possibility that manufacturers would seek dismissal for cases brought under 31 U.S.C. § 3729(a)(1) (2008) and which involved allegations of Medicaid or Medicare Part D fraud (S. Rep. No. 111-10 (2009))
    - Note that prior to *Allison Engine* many districts were in agreement that Medicare and Medicaid were within the purview of § 3729(a)(1)

What Has Changed? (cont.)

- Statute of Limitations
  - Government's filing now relates back to the filing date "of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person" 31 U.S.C. § 3731(c)
  - Government may continue to intervene by either its own Intervening Complaint or amending a qui tam relator's complaint
  - Government may also continue to add claims
  - This provision applies to all cases pending on May 20, 2009

What Has Changed? (cont.)

- Enhanced information sharing provisions for potential FCA plaintiffs
  - Original government agency that intervenes in the case may share the complaint, any other pleadings, and all material evidence and information to other governmental bodies without violating the terms of the seal § 3732(c)
  - Allows DOJ to share evidence obtained from whistleblowers, cooperating witnesses, wiretaps, and other sources with State and local government authorities for any "official use" § 3733(k)(8)
  - Will likely increase the number and sophistication of "me-too" lawsuits by State and local authorities

What has changed? (cont.)

- Broader CID provisions
  - Attorney General may now delegate authority to issue CIDs
  - Information obtained may now be shared with any qui tam relator
  - CIDs are written requests used by the AG or a delagee (such as a US Attorney's Office) when the requestor has reason to believe that any person may be in "possession, custody, or control of any documentary material or information relevant to a false claims law investigation"
  - A CID may require the target to:
    - Produce relevant materials or evidence for inspection and copying
    - Answer written interrogatories
    - Give oral testimony

The Pfizer Case: Brief Overview

- First off-label FCA case with Government intervention to reach conclusion after FERA
  - September 2, 2009 DOJ announced resolution of the investigation
  - The case was prosecuted by the AUSA for D. Mass.
- $2.3 billion settlement reflects the largest ever monetary payment to the United States
- Pfizer subsidiary Pharmacia & Upjohn Company ("Pharmacia"), will pay approximately $1.3 billion in fines and forfeitures to resolve the its criminal charges
- Pfizer will pay approximately $1 billion to settle alleged Federal and State FCA liability

The Pfizer Case: Implications

- The unsealed documents reflect a continuation of the Government's *Parke-Davis* style approach to enforcement
  - Note that D. Mass was the prosecuting authority in the Parke-Davis case
- The allegations for each of the thirteen named products cite wide-spread off-label marketing and kickback payments

The Pfizer Case: Implications (cont.)

- The Pfizer Corporate Integrity Agreement requires an unprecedented level of detailed oversight into sales, marketing, and medical affairs activities that potentially implicate off-label information
- The focus on incentive compensation, call plans, sampling practices, and transparency of payments and authorship suggests a broader role for OIG in regulating off-label marketing
- In sum, the Pfizer CIA explicitly “connects” potential FDCA misbranding violations to potential FCA violations

Implications for Industry Compliance Programs

- FERA codifies many plaintiff and prosecutor-friendly interpretations of the FCA
- While First Amendment protections are still recognized by the Government, the secrecy of pending investigations and the threat of debarment often make it impossible to raise commercial speech defenses in an effective or beneficial manner
- As a result, compliance activities should be proactive, not reactive, and compliance departments should carefully examine cases such as Pfizer to understand where potential pitfalls lie with regard to employee use off-label information

Implications for Industry Compliance Programs (cont.)

- Compliance and Legal personnel should continue to take a “hands-on” approach to compliance
  - Ride alongs with sales force to verify on-label promotion
  - Audits of speaker programs and consultant meetings to ensure that PhRMA guidelines and other professional rules are being followed
  - Oversight and monitoring of Medical Information requests to ensure sales force is not “baiting” unsolicited requests
  - Active role in creating and revising sales call plans, incentive compensation, and sales goals to ensure incentives and targets align with on-label usage

Implications for Industry Compliance Programs (cont.)

- A "culture of compliance" is important in an era where any employee could be a potential witness
  - Companies should examine their existing controls, policies, and procedures regarding use of off-label information
  - Employees should be trained from the executive level down
  - Breaches of company policies regarding off-label information should be dealt with quickly and with appropriate corrective action (e.g. retraining, recall of promotional materials, etc.)
  - Compliance expectations should be communicated to subsidiaries and co-promotion partners to assure consistency among corporate cultures
  - Companies should develop procedures in case employees are contacted by investigators

Questions?

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