

CRITICAL DECISION POINTS IN FALSE CLAIMS ACT LITIGATION

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The Filing of the Complaint

- “Relator” files on behalf of the Government.
- Complaint must be filed in camera and under seal and remain sealed for at least 60 days to allow the Government to investigate the allegations.
- Relator must provide the Government at time of filing with a copy of complaint and written disclosure of substantially all material evidence.

The Intervention Decision

- Once the initial 60-day sealing period has expired, the Government may:
 - 1. Request Court to extend time for good cause shown (see 31 U.S.C. § 3730(b)(3));
 - 2. Intervene and conduct the litigation (see 31 U.S.C. § 3730(b)(4));
 - 3. Decline to intervene and permit the Relator to go forward on his own (Government may intervene at a later date for good cause shown) (see 31 U.S.C. § 3730(e)(4)(8));

The Intervention Decision (cont.)

- 4. Move to dismiss the action (see 31 U.S.C. § 3730(c)(2)(4));
 - 5. Settle the action prior to intervention; or
 - 6. Move to have the complaint partially unsealed to give the Defendant access to the Complaint and allow the Defendant to indicate why it believes intervention is not appropriate.
- Once the Government makes an intervention decision, the complaint is unsealed.

Observations on Intervention

- First significant opportunity for a Defendant to influence the case.
- Defendant should generally seek to persuade the Government to decline intervention.
 - Money is recovered more often in intervened-in cases than declined cases.
 - In FY 2001, of \$1.6 billion recovered, only \$400,000 from declined cases
- Government intervenes in approximately 15% of cases.

Practical Issues

- Government typically will investigate before deciding on intervention. Investigation may take years.
 - A subpoena may indicate existence of a sealed complaint.
 - Negotiate breadth of subpoena – HIPPA venue.
- React immediately to Subpoena/Notice of Complaint
 - Every one “lawyers up.”
 - Joint defense agreement.

Practical Issues (cont.)

- Do not retaliate against whistleblower.
- Start dialogue with government – Theory of defense.
 - Internal investigation.
 - Legal Research.
- FCA's evil twin: Parallel criminal investigation.

Motions: Trees, not the Forest

- Motion to Dismiss for Failure to State a Claim.
 - In order to prevail under the False Claims Act (“FCA”), a Relator or the Government must establish that:
 - 1) The Defendant submitted or caused to be submitted a claim for payment or approval;
 - 2) The claim was false; and
 - 3) The claim was submitted knowingly.
- 31 U.S.C. § 3729(a)(1).

“Caused To Be Submitted”

- Government may claim pharmaceutical company can be held liable for claims submitted by others – physicians and hospitals that submit bills without disclosing discounts for remuneration. Did sales representative give advice on billing? U.S. Ex rel. Walsh v. Eastman Kodak, 98 F. Supp.2d 141 (D. Ma. 2000) (dismissing case against hospital suppliers).

What is False?

- Good faith interpretation of ambiguous regulation (PDMA, Anti-kickback Act, etc)? United States v. Whiteside, 285 F.3d 1345 (11th Cir. 2002).
- No liability for “implied certification” of regulatory compliance, unless payment expressly conditioned on accurate compliance certification. U.S. ex rel. Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001).
- Substandard quality of care: Mikes v. Straus, rejects, but basis for nursing home settlements. Can FDA violations lead to this?

Motions to Dismiss (cont.)

- The complaint may be dismissed pursuant to Rule 12(b)(6) if the Relator or Government is unable to establish the required elements as a matter of law. See United States ex rel. Mobin v. Desert Construction, 87 F.3d 1325 (9th Cir. 1996) (granting defendant's motion to dismiss for failure to state a claim).
- Both the Government and Relator may oppose a motion to dismiss.

Motions to Dismiss (cont.)

- Important to challenge falsity early, particularly in cases involving regulated areas.
 - See U.S. ex rel Schoff v. Royco, Inc., Case No. 01-6010-CIV-DIMITROULEAS, slip op. at 11 (S.D. Fla. July 11, 2002) (dismissing complaint because the presentation of alleged claims “entails no underlying false or fraudulent claim to the Government and is simply not actionable under the False Claims Act”).
- The motion is sometimes successful.
- Frames the motion for summary judgment.

Motion to Dismiss for Failure to Plead Fraud With Particularity

- Complaints filed pursuant to the FCA sound in fraud and are, therefore, required to be pled with particularity pursuant to FRCP 9(b). Bly-Magee v. California, 236 F.3d 1014 (9th Cir. 2001); United States ex rel. Schwartz v. Coastal Healthcare Group, Inc., No. 99-3105, 2000 U.S. App. LEXIS 26914, at *9 (10th Cir. Oct. 26, 2000).

Pleading Fraud With Particularity (cont.)

- Rule 9(b) requires that the Government or Relator identify in the complaint the “who, what, when, where and how” of the fraud and the complaint will be dismissed if it does not. See U.S. ex rel. Clausen v. Lab. Corp. of America, Inc., 290 F. 3d 1301-1312 (11th Cir. 2002).
- Complaint must identify specific claims and describe falsity. Pleading “upon information and belief” is not acceptable. See U.S. ex rel. Walsh v. Eastman Kodak Co., 98 F.Supp. 2d, 141 (D. Mass. 2000).

Observations on Motions to Dismiss for Failure to Plead Fraud with Particularity

- Relator's complaint must comply with Rule 9(b) at the time of filing. Plaintiff is not entitled to discovery to oppose Rule 9(b) motion.
- Court will not allow relator to amend complaint if it would be futile.
- Can be used to limit overbroad discovery by Relator and/or the Government.

Challenging A Relator's Standing

- The FCA generally requires strict compliance with the conditions for filing a qui tam action, and a defendant may file a number of motions to disqualify a Relator if he or she fails to comply.

The most common bases for such motions are:

- “First to File” and
- Public Disclosure/Original Source.

First to File Motion

- “When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.”

37 U.S.C. § 3730(b)(5).

- This provision is generally interpreted broadly to bar subsequent suits based on similar allegations.

Public Disclosure/Original Source

- FCA bars a court from exercising jurisdiction over a qui tam suit based on allegations or transactions that are publicly disclosed unless the Relator is the original source of the information.

31 U.S.C. § 3730(e)(4).

- Two-part test:
 - Was the information publicly disclosed by the media or in other proceeding or investigation;
 - If so, was the Relator the original source of the information.

Observations on Motions Challenging Relators' Standing

- Successful motion:
 - ends case if Government has declined to intervene;
 - simplifies intervened-in case for litigation or settlement; and
 - avoids payment of Relator's attorneys' fees.

Discovery

- One goal of discovery plan is to frame summary judgment motion.
- Serve contention interrogatories early in discovery to compel the Relator or Government to provide the specific factual and legal bases for the allegations in the complaint.
- Depositions should follow to undermine and limit the Relator's and/or Government's specific allegations.

Summary Judgment

- If possible, Defendant should file a motion for summary judgment based on Relator's or the Government's failure to demonstrate the fraud it represented it would show in response to motion to dismiss.

Trial Issues

- Risk of exclusion, multiple penalties pressure defendants to settle even triable cases.
- Bifurcated trial – Bench trial to interpret regulation underpinning FCA claim.
- Let government know litigation is always an option.

Settlement

- Relator is entitled to 15-25 % of recovery in standard cases, depending upon the extent to which the Relator substantially contributed to the prosecution of the action.
31 U.S.C. § 3730(d)(1).
- Government may settle a case without the Relator's consent so long as the court determines, after a hearing, that the settlement is "adequate and reasonable under all the circumstances." 31 U.S.C. § 3730(c)(2)(B).

Observations on Settlement

- Expect follow-on litigation.
 - Payors
 - Class Action
 - Competitors
 - State attorneys general
- Structure settlement to limit follow-on claims.
 - Limit to Medicare specific issues, not commercial payors.
 - Victim is government, not consumers.
- Corporate Integrity Agreement.
- Publicly – traded stock may go up after announcement.

Observations on Settlement (cont.)

- Determining Relator's share can be difficult and result in adversarial filings by Government and Relator.
- Relator's attorneys' fees are often the final hurdle to a negotiated settlement and may be subject to significant negotiation or additional litigation.