

Federal False Claims Act Developments

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Jonathan L. Diesenhaus, Hogan Lovells
Tejinder Singh, Goldstein & Russell

David Wiseman, U.S. Dept. of Justice
Brian Roark, Bass, Berry & Sims

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The Federal False Claims Act

“[A]ny person who:

(A) **knowingly** presents, or causes to be presented, **a false or fraudulent claim** for payment or approval;

(B) **knowingly** makes, uses, or causes to be made or used, a false record or statement **material to a false or fraudulent claim**;

(C) conspires to commit a violation of subparagraph (A), (B), . . . or (G);

* * *

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable . . . for a civil penalty of not less than \$5,000 and not more than \$10,000 [as adjusted for inflation per Pub. L. 104-4101], plus 3 times the amount of damages which the Government sustains because of the act of that person.”

31 U.S.C. § 3729(a)(1)

Key Terms

- **Claim**
 - Any request for government money or property even if the government doesn't hold title (i.e., funds of an occupied nation).
- **Knowingly**
 - Actual knowledge, deliberate ignorance or reckless disregard; no proof of specific intent required.
- **Material**
 - “[A] natural tendency to influence or be capable of influencing.”
- **Obligation**
 - “[E]stablished duty, whether or not fixed, arising from an express or implied... relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.”

31 U.S.C. § 3729(b)

Undefined Key Terms

- **Overpayment**
- **False or Fraudulent**

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Topic 1: Falsity Medically Unnecessary Items or Services

- *U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730 (10th Cir. 2018)
- *Omnicare v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318 (2014)
- *U.S. v. Paulus*, 894 F.3d 267 (6th Cir. 2018)
- *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 733 (7th Cir. 1999)
 (“[T]here is no evidence that Baxter intended to deceive anyone . . . All this record reveals is a dispute about whether Baxter’s testing protocols could be improved. An affirmative answer to that question would not suggest that Baxter’s representations . . . were false or fraudulent.”)
- *U.S. ex rel. Paradies v. AseraCare Inc.*, 176 F.Supp.3d 1282 (N.D. Alabama 2016)

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Topic 2: Materiality

Weighing Evidence of Agency Response

- *Universal Health Services v. Escobar*, 136 S.Ct. 1484 (2016)
 - Misrepresentation “must be material to the Government’s payment decision in order to be actionable under the FCA.”
 - Material means “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”
 - Court need not resolve whether this definition is taken from the Act itself in § 3729(b)(4) or from the common law because “[u]nder any understanding of the concept, materiality ‘look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.’”

Topic 2: Materiality

Weighing Evidence of Agency Response

- *Universal Health Services v. Escobar*, 136 S.Ct. 1484 (2016)
 - Proof of materiality can be “evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases” based on the same noncompliance.
 - **“If the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.”**
 - **“Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.”**

Topic 2: Materiality

Weighing Evidence of Agency Response

- *U.S. ex rel. Prather v. Brookdale*, 892 F.3d 822 (6th Cir. 2018) (reversing district court based on sufficient pleading of materiality regarding timing of need certifications)
- *U.S. ex rel. Campie v. Gilead Scis.*, 862 F.3d 890 (9th Cir. 2017) (materiality found for GMP violations, despite FDA approval and continued payment; court warned that “read[ing] too much into the FDA’s continued approval...would be a mistake”) *CERT PENDING*
- *U.S. ex rel. Ruckh v. Salus Rehab.*, 304 F.Supp.3d 1258 (M. D. Fla. 2018)
- *U.S. ex rel. Rose v. Stephens Inst.*, 901 F.3d 1124 (9th Cir. 2018)

Topic 3: Scierter

Collective and Corporate Knowledge

- *U.S. ex rel. Polukoff v. St. Mark’s Hosp.*, 895 F.3d 730 (10th Cir. 2018)
- *U.S. ex rel. Rigsby v. State Farm Fire & Casualty Co.*, 794 F.3d 457 (5th Cir. 2015)
- *U.S. v. SAIC*, 626 F.3d 1257 (D.C. Cir. 2010)
- *U.S. ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908 (4th Cir. 2003)
- *But see U.S. ex rel. Martin v. Life Care Ctrs. of Am.*, 114 F.Supp.3d 549, 568 (E.D. Tenn. 2014) (allowing the Government to establish scierter “as to the claims identified within the [statistical] sample” by “proffering evidence of [Life Care’s] corporate practices and pressure, and that Life Care knew those practices likely caused the submission of false claims given the complaints it received nationwide from its employees and others”)

Topic 4: Falsity and Damages Patient Assistant Programs

- Dep't of Health and Human Services OIG Advisory Opinion No. 06-04 (Apr. 20, 2006)
- Dep't of Health and Human Services Notice of Modification of OIG Advisory Opinion No. 06-04 (Dec. 23, 2015)
- United Therapeutics DOJ/OIG-HHS Settlement Agreement (2017)
- Pfizer DOJ/OIG-HHS Settlement Agreement (2018)

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