



Drugs and Device: False Claims Act Enforcement Targeting Drug and Device Companies

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2016 FCA Recoveries From Drug and Device Companies

- Over \$2 billion in recoveries from drug and device manufacturers YTD
 - Anti-Kickback Statute: \$440M (6 cases)
 - Off-label promotion: \$495M (6 cases)
 - Price reporting: \$1.25B (2 cases)

Case Developments: Off-Label

- *U.S. ex rel. Colquitt v. Abbott Laboratories f/k/a Guidant Corp.*, 06-cv-01769 (N.D. Tex. 2016)
 - Allegations that defendant encouraged physicians to use biliary stents for unapproved uses
 - Jury verdict for defendant on relator's off-label theory
- Recent cases on limits of pleading of off-label theories:
 - *U.S. ex rel. Polansky v. Pfizer*, 822 F.3d 613 (2d Cir. 2016)
 - *U.S. ex rel. Lawton v. Takeda Pharm. Co.*, 2016 WL 6872652 (1st Cir. 2016)

Case Developments: Off-Label

- *U.S. ex rel. Polansky v. Pfizer, Inc.* (2d Cir. 2016)
 - Affirmed dismissal of claims of improper marketing of Lipitor for use with patients whose cholesterol levels fell outside national guidelines
 - “The FDA does not prohibit physicians, who are free to do so, from prescribing Lipitor for patients with normal cholesterol. Accordingly, it is unclear just whom [defendant] could have caused to submit a ‘false or fraudulent’ claim.”

Case Developments: Off-Label

- *U.S. ex rel. Lawton v. Takeda Pharm. Co.* (1st Cir. 2016)
 - Affirmed dismissal of claims of fraudulent marketing of Type 2 diabetes drug for off-label treatment of prediabetes
 - Court rejected relator’s argument that only the fraudulent statements (e.g. marketing materials) needed to be pleaded with specificity, not the false claims allegedly induced
 - Court found insufficient under Rule 9(b) relator’s allegations of aggregate sales data for off-label prescription; to make his claims more than merely possible, had to identify false claims, either individually or aggregated, from specific providers

Case Developments: AKS

- Anti-Kickback Statute, 42 U.S.C. § 1320a-7b: prohibits offering or receiving any remuneration in return for referrals of items of services reimbursed by federal health programs
- Inducement and the “One Purpose Test”: remuneration violates the AKS if even one of multiple purposes of the payment is to induce referrals
 - But what are the limits on what constitutes an improper purpose?

Case Developments: AKS

- *U.S. ex rel. Ruscher v. Omnicare*, 2016 WL 6407128 (5th Cir. Oct. 28, 2016)
 - Affirmed award of summary judgment to defendant on allegations that specialty pharmacy paid kickbacks to providers by not collecting Part A debt and offering prompt payment discounts to induce referrals
 - Court recognized “one purpose test,” but held “there is no AKS violation, however, where the defendant merely hopes or expects referrals from benefits that were designed wholly for other purposes”
 - Relators did not show that alleged practices were designed to induce referrals

Case Developments: AKS

- *U.S. ex rel. Booker v. Pfizer, Inc.*, 2016 WL 3017381 (D. Mass. May 23, 2016)
 - Awarded summary judgment to defendant on allegation that speaker series was kickback
 - Personal services safe harbor applied and no evidence that it was “really meant to compensate doctors” for prescriptions
 - That defendant tracked its “return on investment” for the speaker series was unremarkable, as only the attendees’—and not the speakers’—prescriptions were tracked

U.S. ex rel. Escobar v. Universal Health Services

- History
 - Teenage Medicaid beneficiary died after receiving treatment from unlicensed and unsupervised professionals
 - Parents filed complaints with several state agencies and a *qui tam* action
 - *Qui tam* suit alleged that lack of compliance with state regulations governing staff qualification and supervision rendered claims “false”

U.S. ex rel. Escobar v. Universal Health Services

- Implied certification is a viable theory of liability “at least in certain circumstances”:
 - (1) if the claim submitted by the defendant, in addition to requesting payment, “makes specific representations about the goods and services provided;” and
 - (2) “the defendant’s failure to disclose noncompliance with material statutory, regulatory or contractual requirement makes those representations misleading half-truths.”
- The underlying statute, regulation, or contractual provision need not *expressly* state it is a condition of payment.

First Condition: Specific Representations

- Implied certification can be a basis for liability “at least” where two conditions are satisfied. The first condition is that “the claim does not merely request payment, but also makes specific representations about the goods or services provided.”
 - *Escobar*: UHS submitted claims with payment codes that corresponded to specific counseling services and used NPI numbers that corresponded to specific job titles

Second Condition: Materiality

- Implied certification can be policed through the FCA’s “materiality” and “scienter” requirements
 - Materiality “look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.”
 - Violation is “material” if:
 - “A reasonable man would attach importance to [the misrepresented information] in determining his choice of action in the transaction”; or,
 - “the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter ‘in determining his choice of action,’ even though a reasonable person would not.”

Second Condition: Materiality

- Court holds that “materiality cannot rest on ‘a single fact or occurrence as always determinative.’” But, Court gives the following guidance for determining materiality:
 - Government’s right to refuse payment if aware of the violation is insufficient, by itself, to demonstrate materiality
 - Noncompliance cannot be minor or insubstantial
 - Proof can include, but is not limited to, “evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory or contractual requirement”
 - Government’s payment of “particular claim,” or practice of paying “particular type of claims,” with “actual knowledge” of violation of certain requirements, is “strong evidence” that those requirements are not material

Escobar's “Two Conditions”

- Some courts applying *Escobar* appear to assume, without expressly deciding, that *both* conditions be satisfied for implied certification
 - See, e.g., *U.S. v. Sanford-Brown*, 840 F.3d 445 (7th Cir. 2016) (holding no implied cert liability because relator failed to plead a “specific representation”)
- Others have expressly refused to require pleading both conditions
 - See, e.g. *Rose v. Stephens Institute*, 2016 WL 5076214 (N.D. Cal. Sept. 20, 2016)

Escobar's “Two Conditions”

- *Rose v. Stephens Institute*, 2016 WL 5076214 (N.D. Cal. Sept. 20, 2016)
 - In denying defendant’s MSJ, court rejected the argument that *Escobar* established a “two-part test” for implied certification
 - “The language in *Escobar* that [defendant] relies upon does not purport to set out, as an absolute requirement, that implied certification can attach only when these two conditions are met
 - Question certified for interlocutory appeal to the Ninth Circuit
- See also *U.S. ex rel. Panarello v. Kaplan Early Learning Co.*, 11-cv-353 (W.D.N.Y. Nov. 14, 2016) (same)

Applying the “Materiality” Standard

- *U.S. ex rel. Escobar v. Universal Health Servs.*, 2016 WL 6872650 (1st Cir. Nov. 22, 2016) (remand)
 - Held plaintiff sufficiently alleged noncompliance was “material” because (1) the regulation was a condition of payment (which the court noted was relevant, though not dispositive), and (2) because compliance with the rule went to the essential nature of the services being reimbursed

Applying the “Materiality” Standard

- *U.S. ex rel. Escobar v. Universal Health Servs.*, 2016 WL 6872650 (1st Cir. Nov. 22, 2016) (remand)
 - First Circuit also rejected defendant’s argument of no materiality due to government knowledge
 - Court reasoned that the complaint did not allege government knowledge of noncompliance, and this was a factual issue that could be developed further in discovery

Audience Questions?



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