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The False Claims Act and Off-Label Promotion:

Understanding and Minimizing the Risks for Pharmaceutical Manufacturers

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Overview of FDA Rules on Promotion

- Under the FDCA, new drugs cannot be distributed in interstate commerce unless the sponsor demonstrates to the FDA that the drug is safe and effective for each of its intended uses. 21 USC Sec. 355(a) & (d).
- Though physicians may prescribe a drug for a use other than the one for which it is approved, the FDA prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. 21 USC Sec. 331(d), 355(a).
- In some contexts, dissemination of information on unapproved uses may be viewed by FDA as promotional labeling or advertising that fails to meet FDA regulatory requirements and therefore constitutes unlawful off-label promotion in violation of the FDCA.

Overview of Reimbursement Rules

- Medicaid reimbursement is available only for "covered outpatient drugs," *i.e.,* drugs used for a "medically accepted indication." 42 USC Sec. 1396b(i)(10).

- A medically accepted indication includes: (1) an FDA-approved indication, and (2) certain other indications in specified drug compendia. *Id.* Sec. 1396r-8(k)(6), Sec. 1396r-8(g)(1)(B)(i).

- Medicaid reimbursement is not available for indications outside these two categories.

Overview of the False Claims Act

- The False Claims Act imposes liability upon any person who:

  "(1) knowingly presents, or causes to be presented, to … the United States Government … a false or fraudulent claim for payment or approval; [or] (2) knowingly makes or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 USC Sec. 3729.

- While pharmaceutical manufacturers do not generally submit claims directly to the Federal government, they can be held liable under the FCA for "causing" a false claim to be submitted (*e.g.,* by a physician).

- "Knowingly" is defined in the FCA to mean acting: (1) with actual knowledge, (2) in reckless disregard, or (3) deliberate ignorance of the truth or falsity of the claim.

What's the Link?

- Some prosecutors and private citizens take the view that the submission of an off-label prescription -- *i.e.,* a not-covered outpatient drug -- for Medicaid reimbursement is a material misrepresentation made to obtain a government benefit and therefore constitutes a false claim under the FCA.
  - "Material" -- where the government would not have paid it it had known the Rx was off-label
- Where a manufacturer's knowing conduct "causes" the submission, there is FCA liability.

False Claims Act

- The elements of an FCA violation -- including knowledge, materiality and causation -- need only be proved by a "preponderance of the evidence," not the "beyond a reasonable doubt" standard applicable to criminal cases.

- Prosecutors like the FCA because of its broad scope of liability, expansive definition of "knowledge," and lesser burden of proof.

False Claims Act -- Penalties

- Violations of the FCA are punishable by:
  - Statutory civil penalties of $5,000-$11,000 per false claim.
  - Treble damages.
- In the pharma context, each prescription arguably constitutes a separate "claim." In a case involving 10,000 prescriptions, minimum liability could be $50,000,000 (plus treble damages).
- Liability is imposed on individuals and corporations.
- These penalties are separate and distinct from criminal liability under the FDCA and/or other applicable laws.
- Related risks -- exclusion from healthcare reimbursement programs (not mandatory for FCA violations); CIAs, state Attorney General consumer protection actions.

False Claims Act -- Whistleblowers

- Private citizens ("relators") may file complaints alleging violations of the FCA. A whistleblower can be virtually anyone -- including a current or former employee, a customer, a competitor. These suits are often called "qui tam" actions.
- Once a whistleblower suit is filed, the government must decide whether to take over and prosecute the suit ("intervene"). If not, the relator may proceed on his/her own.
- A whistleblower is entitled to receive up to 30% of any eventual recovery by the government.
- Virtually every major health care fraud/abuse case in recent years started as a whistleblower complaint.

Off-Label Promotion and the FCA

- In the Parke-Davis case, an employee who worked at Parke-Davis for five months filed a whistleblower suit alleging various unlawful off-label promotional activities.
- The relator alleged that:
  - such activities caused physicians to write prescriptions for off-label uses for which Medicaid reimbursement was not available;
  - the prescriptions were reimbursed by various state Medicaid agencies; and
  - Parke-Davis thereby caused false claims to be submitted.
- The U.S. Department of Justice has filed a "statement of interest" in support of the relator's legal theories but has not intervened in the case.

Off-Label and the FCA (cont'd)

- In two significant decisions, the U.S. District Court in Boston has endorsed many of the relator's legal theories. United States v. Parke-Davis, 147 F.Supp.2d 39 (D.Mass. 2001); United States v. Parke-Davis, 2003 WL 22048255 (D. Mass. Aug. 22, 2003).

- An off-label prescription submitted for reimbursement by Medicaid is a false claim under the FCA.

- FCA liability arises -- not from the unlawful off-label marketing activity itself -- but from the submission of Medicaid claims for uncovered off-label uses "caused" by a manufacturer's conduct.

Off-Label and the FCA (cont'd)

- The standard for "causation" under the FCA is whether the submission of false claims was "reasonably foreseeable" from a defendant's conduct, and it is reasonably foreseeable that physicians and pharmacists would submit false Medicaid claims in response to unlawful off-label promotional activities by a pharmaceutical manufacturer (*I.e.,* the activities were a "substantial factor" in causing the claims).
  - What activities can "cause" a claim to be submitted?
  - In Parke-Davis, the court said off-label marketing and financial incentives, like kickbacks" would suffice -- not the fact of off-label promotion itself

Off-Label and the FCA (cont'd)

- Under Sec. 3729(a)(I), the off-label statements of a manufacturer do not themselves need to be false or fraudulent. Unlawful -- but truthful -- promotion of off-label uses to physicians that treat Medicaid patients can give rise to FCA liability (where there are other activities causing the claims to be submitted).
  - But the Court's language (on previous slide) appears to say truthful off-label promotion, alone, may not be enough

- The Parke-Davis case is still in the preliminary motions stage, and the Court has assumed (as it must) that the allegations are true.
  - "Relator's theory of liability takes the parties into territory not well charted by existing decisional law."

Reducing Your Risk: Conducting An Off-Label Assessment

- Identify key products with potential off-label uses
- Compile and review policies and procedures that address off-label uses
- Evaluate adequacy of existing training programs on off-label compliance issues
- Review relevant complaints to internal hotline or other internal reporting mechanisms
- Review any recent FDA regulatory actions, whistleblower suits, judicial decisions, settlements
- Review complaints from competitors
- Review internal/company documents on off-label issues
- Assess compliance program

Reducing Your Risk: Special Areas for Review

- Promotional materials
- Medical liaisons
- Funding for medical education
- Requests for off-label information
- Marketing plans
- Compensation of sales representatives
- Consulting and preceptorship arrangements with physicians
- Samples

Reducing Your Risk: Procedural Issues

- Violations of off-label promotional rules may result in significant criminal or civil exposure.
- Structure any review to protect applicable privileges
- Companies under CIAs may have special obligations
- The PDMA regulations require manufacturers to disclose violations to the FDA

Fine Print

- Previous slides summarize some of the key provisions of the False Claims Act and the rules and regulations governing promotion and reimbursement of pharmaceutical products. The information provided does not constitute legal advice.

- In a number of instances, slides describe general rules or provisions of the applicable laws; however, because space is limited, various exceptions or qualifications may be relevant that are not mentioned in the slides.

- Views expressed herein and during the presentation are mine, and do not necessarily represent the views of Arnold & Porter or its clients.