New Government Theories of Civil Liability for Off-Label Promotion: Are They Legitimate?

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## Civil False Claims Act Liability for Off-Label Promotion

### Civil Off-Label Settlements

<table>
<thead>
<tr>
<th>Company</th>
<th>Civil Penalty</th>
<th>Date of Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genentech</td>
<td>$20 M</td>
<td>1999</td>
</tr>
<tr>
<td>Parke-Davis</td>
<td>$190 M</td>
<td>2003</td>
</tr>
<tr>
<td>Schering-Plough</td>
<td>$255 M</td>
<td>2006</td>
</tr>
<tr>
<td>Cell Therapeutics</td>
<td>$10.5 M</td>
<td>2007</td>
</tr>
<tr>
<td>Medicis</td>
<td>$9.8 M</td>
<td>2007</td>
</tr>
<tr>
<td>Purdue Pharma LP</td>
<td>$130 M</td>
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</tr>
<tr>
<td>Jazz Pharmaceuticals/Orphan Medical</td>
<td>$2.8 M</td>
<td>2007</td>
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<tr>
<td>Otsuka Pharmaceutical</td>
<td>$4 M</td>
<td>2008</td>
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<tr>
<td>Cephalon</td>
<td>$374.9 M</td>
<td>2008</td>
</tr>
</tbody>
</table>
Promotion and Claims

Manufacturer Liability?

- (If False)

Manufacturer

- Off-Label Promotion
- MD
- Claim

Manufacturer

- Off-Label Promotion
- MD Not Influenced
- MD Influenced
- Claim

Manufacturer

- Off-Label Promotion
- MD Not Influenced
- MD Influenced
- Claim

- Misrepresents Material Facts
- Material False Certification
- Other

- ?
Factual Falsity?

| 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate Items 1, 2, 3 or 4 to Item 24E by Line) |
| D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) |

**SIDLEY AUSTIN**
False Certification?

SIGNATURE OF PHYSICIAN (OR SUPPLIER): I certify that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction.
False Implied Certification – Of What?

The District Court of Massachusetts “has held that illegal off-label marketing that results in the submission of impermissible claims for reimbursement states a claim under the FCA...” Proof of falsity could entail a showing that the provider sought payment from a federal health care program for a use that was off-label and not covered by that program.

“In any event, even Parke-Davis concedes that eight states do not provide reimbursement for off-label drug prescriptions and in those states, a Medicaid reimbursement request for an off-label, non-compendium prescription from a federal health care program constitutes a false claim.”


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“It cannot be an actionable violation of the FCA for an individual to promote truthful information to the government, in order to allow the government to determine whether or not the information establishes eligibility for a certain program.”


Carrier decisions subject to appeal.

“With the exception of claims that are properly coded and submitted to Medicare, the mere fact that a claimant’s submission was denied does not give rise to a cause of action under the FCA.”


Liability only attaches to following situations on a false claim:

- Proof of falsity could entail a showing that the provider sought payment from a federal health care program for a use that was off-label and not covered by that program.

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“Drugs” covered under Medicare Part B include any drugs or biologicals “used in an anti-cancer chemotherapeutic regimen for a medically accepted indication.”

42 U.S.C. § 1395x(t)(2)(A)

“Medically accepted indication” is defined to include:

(a) any FDA-approved use;

(b) any other use of an FDA-approved drug if it is supported by one or more citations in certain compendia, or

(ii) determined by the carrier to be “medically accepted based on supportive clinical evidence in peer-reviewed medical literature...”

Id. at § (t)(2)(B)

“A claim may be rendered false if drug manufacturer falsified studies or engaged in other unlawful, fraudulent conduct in the promotion of a drug or to procure FDA approval or inclusion in a compendium.”

United States’ Statement of Interest in Response to Defendant’s Motion Dismiss in United States ex rel. Rost v. Pfizer, 2008 WL 3049067 (May 12, 2008)

Manufacturer → Off-Label Promotion → Submitter → Claims → Manufacturer Liability?
New Government Theory of Liability: "Fraudulent" Claims

The False Claims Act was intended not only by a pejorative term to describe government payments for false or fraudulent claims. To the contrary, the legislative history of the statute and relevant case law support the proposition that where a claim for payment is the result of a fraudulent process—bid-rigging, self-dealing, etc.—such that the reliability and trustworthiness of the claim is compromised, the claim may be treated as false under the FCA despite its facial accuracy.


“The FCA is not designed to punish every type of fraud committed against the Government. FCA is not a regulatory vehicle, and its scope should not be expanded to include every instance where a claimant fails to comply with all applicable regulations.”

United States ex rel. Riley v. St. Luke’s Episcopal Hospital, et al., 232 F.3d 749 (5th Cir.2001)


"The FCA is not intended to operate as a stalking horse for enforcement of every statute, rule, or regulation. To hold that the mere submission of a claim for payment, without more, constitutes an implied certification of compliance with the conditions of the Government program seriously undermines this principle."

- Bid-rigging (Marcus v. Hess)
- Falsifying Eligibility (Island Park)
- Self-dealing/collusion (Dynamics Research)

All cases in which the defendant — a direct submitter of claims — rigged the process, thereby rendering all claims false. As a result, Government money ended up in the hands of people who were ineligible.

- Theory proves too much: In the off-label situation, physicians are lawfully entitled to submit off-label claims (at least those that are covered)
- Those claims are not rendered “false” or “fraudulent” by any action of a manufacturer
- Thus, at most, this theory only gets at some additional claims, not all claims

Manufacturer → Off-Label Promotion → Submitter → Claims → Manufacturer Liability?
The Specificity Requirement

• In cases in which liability may or may not result from conduct, specific pleading is essential

“In this case, the relators have provided detailed allegations of various schemes to promote Marinol’s off-label use, but their allegations that the defendants’ alleged illegal marketing campaign caused the submission of false claims for government reimbursement totaling millions of dollars are not supported by any facts concerning false claims actually submitted to the government for reimbursement.

The relators speculate that a false claim must have been submitted to the government, arguing that “it is possible, for example, that someone submitted a false claim to the government related to Marinol prescriptions for Marinol rose from 10,367 in 2000 to 124,208 in 2004, and Medicaid reimbursements for Marinol rose from $21.6 million in 2000 to $62 million in 2005” (Doc. 92, p. 9). However, the Eleventh Circuit will not infer that a false claim was submitted to the government, even when the relator provides detailed allegations of the fraudulent scheme that purportedly gave rise to the false claim.”

The Specificity Requirement

• Unfortunately, the Government does not agree:

“[D]efendants seek to impose too rigid a pleading standard in FCA cases...[I]n off-label cases, where the alleged false claims were submitted not by the defendant, but instead by a third party, a relater need not allege the details of particular claims, so long as the complaint as a whole is sufficiently particular to pass muster under the FCA...”

United States’ Statement of Interest in Response to Defendant’s Motion Dismiss in United States ex rel. Rost v. Pfizer, 2008 WL 3049067 (May 12, 2008)
The Government v. The Defense

ALL CLAIMS

-Facially False Claims
-Claims Directly Induced by Fraudulent Statements?

Manufacturer → Doctor

Off-Label Promotion
Who Will Prevail?
The End