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BEIJING BRUSSELS CHICAGO DALLAS FRANKFURT GENEVA HONG KONG LONDON LOS ANGELES NEW YORK SAN FRANCISCO SHANGHAI SINGAPORE TOKYO WASHINGTON, D.C.

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

Presentation to Ninth Annual Pharmaceutical Regulatory Compliance Congress

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Civil False Claims Act Liability for Off-Label Promotion

Civil Off- Label Settlements

Company	Civil Penalty	Date of Resolution
Genentech	$20 M	1999
Parke-Davis	$190 M	2003
Schering-Plough	$255 M	2006
Cell Therapeutics	$10.5 M	2007
Medicis	$9.8 M	2007
Purdue Pharma LP	$130 M	2007
Jazz Pharmaceuticals/ Orphan Medical	$2.8 M	2007
Otsuka Pharmaceutical	$4 M	2008
Cephalon	$374.9 M	2008

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Promotion and Claims

Manufacturer Liability?

Manufacturer → Off-Label Promotion → MD → Claim — ✓ (If False)

Manufacturer → Off-Label Promotion → MD Not Influenced → Claim — —

Manufacturer → Off-Label Promotion → MD Influenced → Claim — ✓ (If False)

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

Manufacturer → Off-Label Promotion → MD Influenced → Claim

- Misrepresents Material Facts — ✓
- Material False Certification — ✓
- Other — ?

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Factual Falsity?

1500

HEALTH INSURANCE CLAIM FORM

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)

SAMPLE

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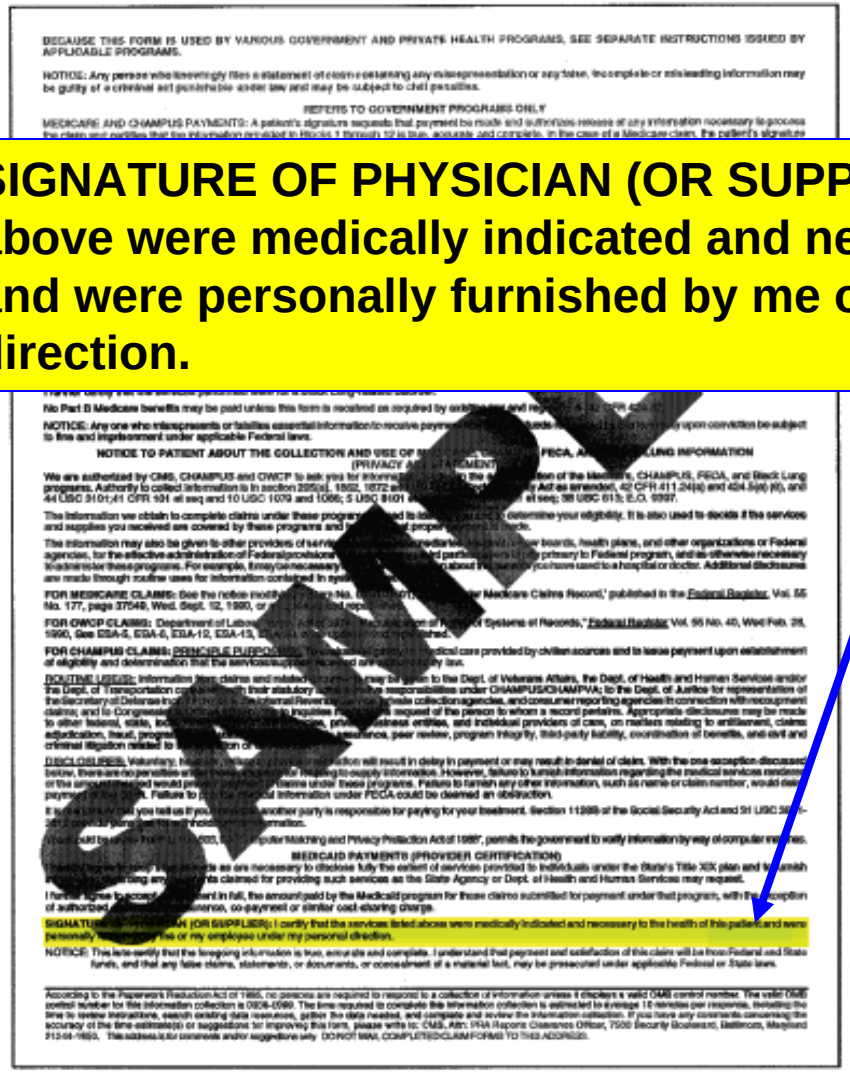
False Certification?

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.



BECAUSE THIS FORM IS USED BY VARIOUS GOVERNMENT AND PRIVATE HEALTH PROGRAMS, SEE SEPARATE INSTRUCTIONS ISSUED BY APPLICABLE PROGRAMS.

NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.

REFERS TO GOVERNMENT PROGRAMS ONLY

MEDICARE AND CHAMPUS PAYMENTS: A patient's signature requests that payment be made and authorizes release of any information necessary to process the claim and certifies that the information provided in Blocks 1 through 12 is true, accurate and complete. In the case of a Medicare claim, the patient's signature

No Part B Medicare benefits may be paid unless this form is received as required by exi

NOTICE: Any one who misrepresents or falsifies essential information to receive payme upon conviction be subject to fine and imprisonment under applicable Federal laws.

NOTICE TO PATIENT ABOUT THE COLLECTION AND USE OF S FECA, A LUNG INFORMATION

(PRIVACY A STATEMENT

We are authorized by CMS, CHAMPUS and OWCP to ask you for informa tion of the Medicare, CHAMPUS, FECA, and Black Lung programs. Authority to collect information is in section 205(a), 1862, 1872 a Act as amended, 42 CFR 411.24(a) and 424.5(a)(6), and 44 USC 3101;41 CFR 101 et seq and 10 USC 1079 and 1086; 5 USC 8101 et seq; 38 USC 513; E.O. 9397.

The information we obtain to complete claims under these program determine your eligibility. It is also used to decide if the services and supplies you received are covered by these programs and

The information may also be given to other providers of servic boards, health plans, and other organizations or Federal agencies, for the effective administration of Federal provisions primary to Federal program, and as otherwise necessary to administer these programs. For example, it may be necessary about the services you have used to a hospital or doctor. Additional disclosures are made through routine uses for information contained in sys

FOR MEDICARE CLAIMS: See the notice mod Medicare Claims Record," published in the Federal Register, Vol. 55 No. 177, page 37549, Wed. Sept. 12, 1990, or

FOR OWCP CLAIMS: Department of Labo Systems of Records," Federal Register Vol. 55 No. 40, Wed Feb. 28, 1990, See ESA-5, ESA-6, ESA-12, ESA-13,

FOR CHAMPUS CLAIMS: PRINCIPLE PURPO medical care provided by civilian sources and to issue payment upon establishment of eligibility and determination that the services/supp by law.

ROUTINE USES: Information from claims and related given to the Dept. of Veterans Affairs, the Dept. of Health and Human Services and/or the Dept. of Transportation co with their statutory responsibilities under CHAMPUS/CHAMPVA; to the Dept. of Justice for representation of the Secretary of Defense in Internal Revenue collection agencies, and consumer reporting agencies in connection with recoupment claims; and to Congressi inquiries made at the request of the person to whom a record pertains. Appropriate disclosures may be made to other federal, state, and business entities, and individual providers of care, on matters relating to entitlement, claims adjudication, fraud, program assistance, peer review, program integrity, third-party liability, coordination of benefits, and civil and criminal litigation related to

DISCLOSURES: Voluntary, failure will result in delay in payment or may result in denial of claim. With the one exception discussed below, there are no penalties failing to supply information. However, failure to furnish information regarding the medical services rendered or the amount charged would pr claims under these programs. Failure to furnish any other information, such as name or claim number, would delay payment of your claim. Failure to information under FECA could be deemed an obstruction.

If you tell us that you have another party is responsible for paying for your treatment, Section 1128B of the Social Security Act and 31 USC 3801-3812 prohibit false statements or information.

Information could be used in Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches.

MEDICAID PAYMENTS (PROVIDER CERTIFICATION)

as are necessary to disclose fully the extent of services provided to individuals under the State's Title XIX plan and to furnish ing any claimed for providing such services as the State Agency or Dept. of Health and Human Services may request.

I hereby agree to accept ent in full, the amount paid by the Medicaid program for these claims submitted for payment under that program, with the exception of authorized deductible, co-insurance, co-payment or similar cost-sharing charge.

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.

NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0999. The time required to complete this information collection is estimated to average 15 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. This address is for comments and/or suggestions only. DO NOT MAIL COMPLETED CLAIM FORMS TO THIS ADDRESS.

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False Implied Certification – Of What?

- Many off-label uses are reimbursed
- But suppose they are not – How does that create liability?

Manufacturer liability?

– Liability only attaches to knowing submission of false claims
– Reimbursement is often left to discretion of carriers
– Providers have considerable discretion to determine whether reimbursable
– Carrier decisions subject to appeal

Manufacturer → Promotion → Influenced → Off-label → Claim → Covered / Not Covered ✓

Is this legally correct?

No

"In any event, even Parke-Davis concedes that eight states do not provide reimbursement for off-label drug prescriptions not included in a medical compendium, and in those states, a Medicaid reimbursement request for an off-label non-compendium prescription is thus factually and legally constitutes a false claim."

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 a provider sought payment from a federal health care program for a use that was off-label and not covered by that program."

United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39 (D. Mass. 2001)

"Drugs" covered under Medicare Part B include any drugs or biologicals "used in an anticancer chemotherapeutic regimen for a medically accepted indication." 42 U.S.C. § 1395x(t)(2)(A)

"Medically accepted indication" is defined to include:

"(b) any other use of an FDA approved drug …

(i) 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)

"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 that information establishes eligibility for a certain program."

U.S. ex rel. Burlbaw v. Orenduff, 400 F.Supp.2d 1276 (Nov. 15, 2005)

"With the exception of claims that are properly coded and submitted to Medicare solely for the purpose of obtaining a written denial, physician practices are to bill the Federal health programs only for items and services that are covered."

OIG Compliance Program Guidance for Small Group Practices, 65 Fed. Reg. 59434, 59445 (Oct. 5, 2000)

- If proof of non-covered claim is not sufficient, then what?

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

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New Government Theory of Liability: "Fraudulent" Claims

"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)

New Government Theory of Liability: "Fraudulent" Claims

						Manufacturer Liability?
Manufacturer	Off-Label → Promotion	Submitter	→	Claims		✓

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New Government Theory of Liability: “Fraudulent” Claims

“...The False Claims Act is violated not only by a person who makes a false statement or a false record to get the government to pay a claim but also by one who engages in a fraudulent course of conduct that causes the government to pay a claim for money.”

[illegible] fraudulent attempts to cause the Government to pay out sums of money.”

United States v. The Incorporated Village of Island Park, 888 F. Supp. 419 (EDNY 1995)

Ab-Tech Construction Inc. v. United States, 31 Fed. Cl. 429 (1994)

“The fact that a claim is facially accurate does not preclude liability under the FCA. 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 a claim is compromised, the claim may be considered false under the FCA despite its facial accuracy.”

United States v. Dynamics Research Corp., 432 F. Supp. 2d 175 (D. Mass. 2006)

“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, always constitutes an implied certification of compliance with the conditions of the Government program seriously undermines this principle.”

United States ex rel. Joslin v. Community Home Health of Maryland, Inc. 984 F. Supp. 374 (D. Md. 1997)

“The FCA is not a regulatory vehicle, and its scope should not be broadened 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., 252 F.3d 749 (5th Cir.2001)

“...FCA is not designed to punish every type of fraud committed against the Government.”

U.S. v. McNinch, 356 U.S. 595 (1958)

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New Government Theory of Liability: "Fraudulent" Claims

- 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.

New Government Theory of Liability: "Fraudulent" Claims

- 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 Liability?

Manufacturer → (Off-Label / Promotion) → Submitter → Claims ?

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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 to draw a strong inference that physicians prescribed Marinol as result of Solvay's off-label marketing campaign, because over the life of that illegal campaign, 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."

Hopper v. Solvay Pharmaceuticals, Inc., 2008 WL 4177927 (M.D. Fla. Sept. 8, 2008)

"At most, Rost raises facts that suggest fraud was possible, but the complaint contained no factual or statistical evidence to strengthen the inference of fraud beyond possibility. It may well be that doctors who prescribed Genotropin for off-label uses as a result of Pharmacia's illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients. It may be that physicians prescribed Genotropin for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it. Rost did not plead enough to satisfy the concerns behind Rule 9(b)."

United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720 (1st Cir. 2007)

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The Specificity Requirement

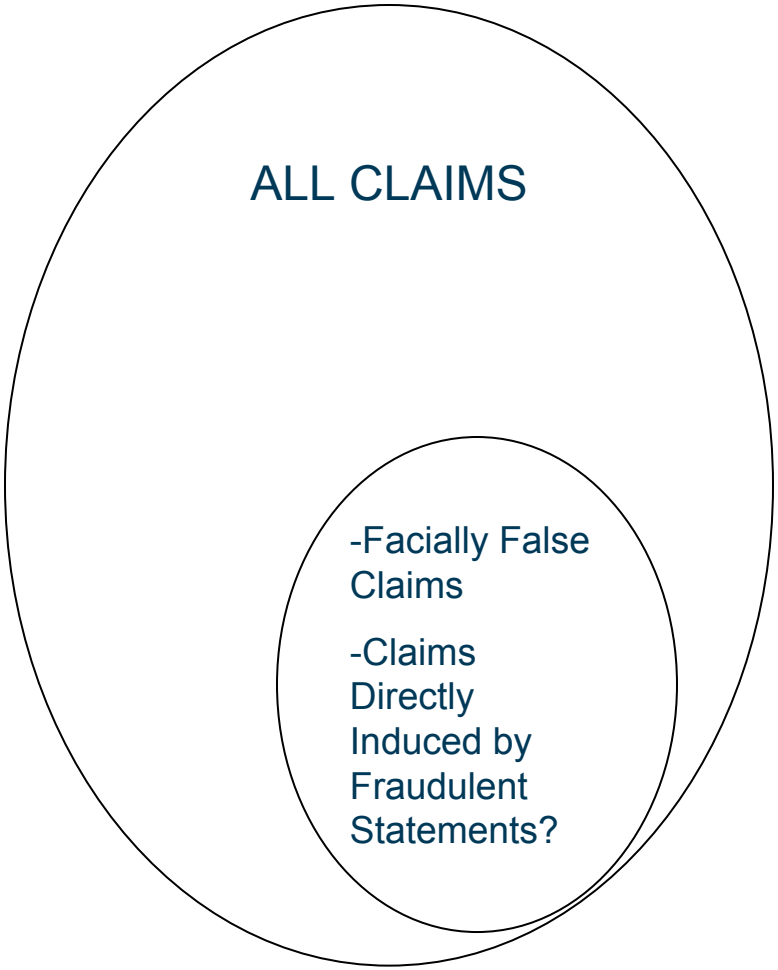
- Unfortunately, the Government does not agree:

  "[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

Manufacturer → Off-Label Promotion → **Doctor** →



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Who Will Prevail?

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The End