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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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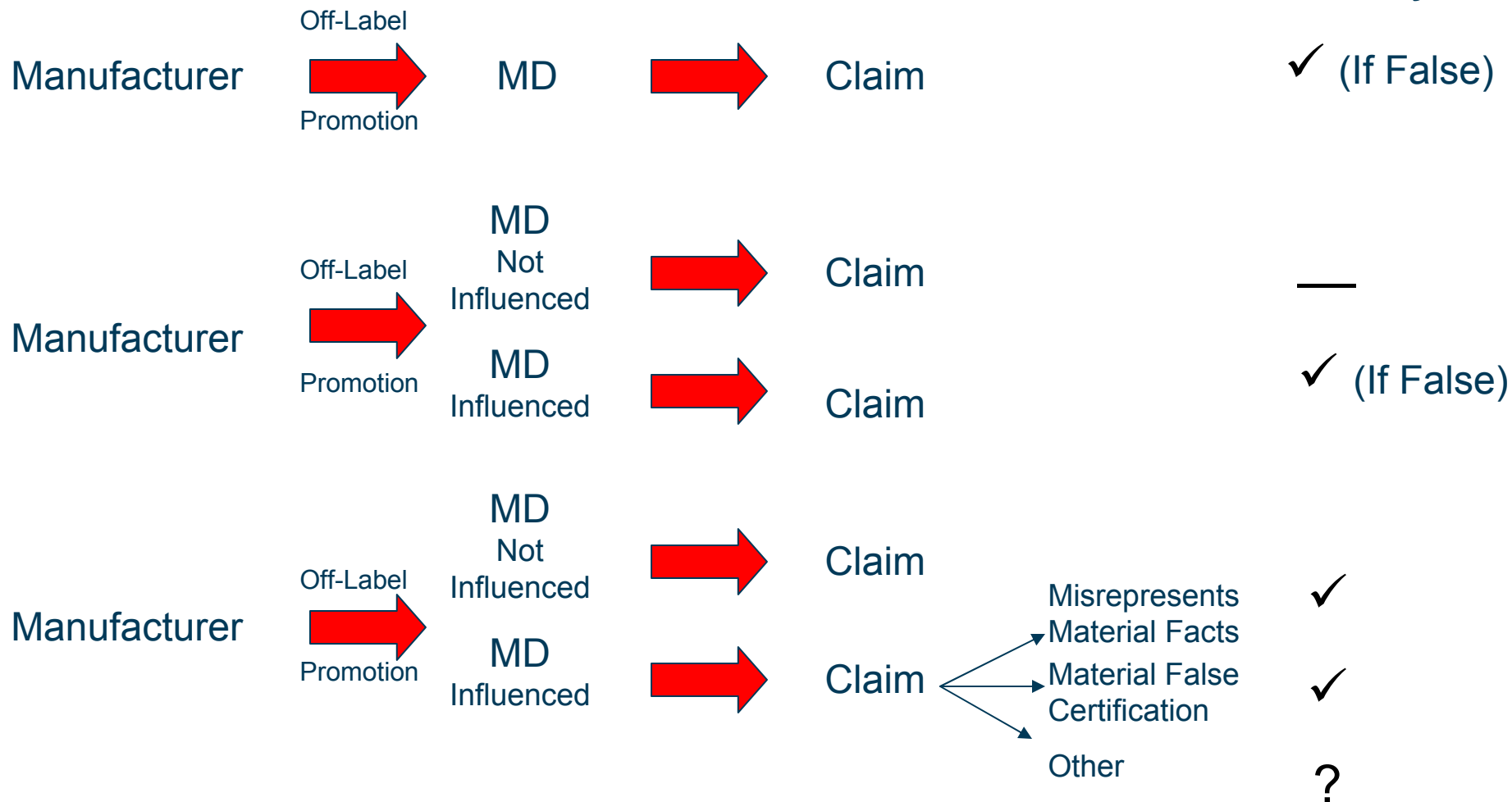
Civil False Claims Act Liability for Off-Label Promotion

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

Promotion and Claims

Manufacturer Liability?



Factual Falsity?

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 6090

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY

D. PROCEDURE CODES

SAMPLE

NLUCC Instruction Manual available at: www.nlucc.org PLEASE PRINT ON TYPE APPROVED CMS-0088-0900 FORM CMR-1500 (06-99)

D. PROCEDURES, SERVICES, OR SUPPLIES
(Explain Unusual Circumstances)

False Certification?

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 Boxes 1 through 10 is true, accurate, and complete. In the case of a Medicare claim, the patient's signature

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.

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No Part D Medicare benefits may be sold unless this form is received or received by exhibitors and received by 4-30-2014 424-121

NOTICE: Any one who misrepresents or falsifies essential information to receive payment from the Trade Readjustment Assistance Fund may, upon conviction, be subject to fine and imprisonment under applicable Federal laws.

NOTICE TO PATIENT ABOUT THE COLLECTION AND USE OF MEDICAL INFORMATION FOR RESEARCH PURPOSES AND FOR THE PROTECTION OF YOUR INFORMATION

We are authorized by CMS, CHAMPUS and OWCP to ask you for information for the administration of the Medicare, Medicaid, and Black Lung programs. Authority for collection of information is in section 225(a), 1902, 1972 and 44 USC 3101; 41 CFR 101-11.4 and 10 USC 1009 and 1006; 50 USC 4601. We will not release your information to anyone except as authorized by law. For more information, call 1-800-540-7077.

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

The information may also be given to other providers of services, intermediaries, and other boards, health plans, and other organizations or Federal agencies, for the effective administration of Federal provisions, and to other parties having a primary or secondary interest in the program, and as otherwise necessary.

to adhere to these programs. For example, they can necessary
are made through routine uses for information contained in systems

FOR MEDICARE CLAIMS: See the notice in this issue, page No. 10, for information on the Medicare Claims Record, published in the Federal Register, Vol. 55, No. 177, page 37548, Wed. Sept. 12, 1990, or for a copy, contact your nearest Social Security Administration office.

FOR OWCP CLAIMS: Department of Labor, Office of Workers' Compensation Programs, "Federal Register" Vol. 95 No. 40, Wed Feb. 29, 1990. See EGA-5, EGA-6, EGA-12, EGA-13, EGA-14, and EGA-15, and references.

FOR CHAMPUS CLAIMS: DOMESTIC PURPOSES - For active military medical care provided by civilian sources and to issue payment upon establishment of eligibility and determination that the services were rendered on active duty leave.

FOIA b (7)(C). Information from this document is withheld from public release under the provisions of 5 U.S.C. 552(b)(7)(C) because disclosure of the information could reasonably result in the identification of confidential sources and the disclosure of confidential information to the Dept. of Veterans Affairs, the Dept. of Health and Human Services and/or the Dept. of Transportation consistent with their statutory duties. The responsibility under 50 U.S.C. 3605(a) for the collection, dissemination, and use of information is placed solely on those individuals or organizations that collect, disseminate, or use the information. This document contains information from the Department of Defense and the Department of Justice, and is not to be released to the public without the approval of the Secretary of Defense and the Attorney General.

claims, and to Congress and the courts. It requires the release of the record to the person to whom a record pertains. Appropriate disclosures may be made to other federal, state, local, or foreign government agencies, private business entities, and individual providers of care, on matters relating to entitlement, claims, or benefits. The act also requires that records be maintained in a manner that allows for retrieval and release of records.

insurance, peer review, program integrity, third-party activity, coordination of benefits, and care at a

below. There are no penalties or sanctions for failing to supply information. However, failure to furnish information regarding the medical services rendered or the amount received would preclude the claimant from receiving benefits under these programs. Failure to furnish any other information, such as name or claim number, would result in denial of the claim.

It is important that you tell us if you think another party is responsible for paying for your treatment. Section 1109B of the Social Security Act and 51 USC 3605-10-101

It should be noted that the 2002, 2003 Computer Matching and Privacy Protection Act of 1988¹ permits the government to verify information by way of computer matches.

MEDICAID PAYMENTS (PROVIDER CERTIFICATION)
 I hereby certify that I am a duly licensed provider of services as defined in the State's Title XIX plan and I am not a provider of services under the plan of another state. I am not a provider of services under the plan of another state. I am not a provider of services under the plan of another state.

I further agree to accept, in full, the amount paid by the Medicaid program for these claims submitted for payment under that program, with the exception of authorized, non-covered or denied services.

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 performed in accordance with my certification or my accreditation to perform the services indicated.

NOTICE: This letter certifies 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.

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SIDLEY AUSTIN
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False Implied Certification – Of What?

The District Court of Massachusetts “has held that
 “In any event, even Parke-Davis concedes that eight

- Many states do not provide reimbursement for off-label drug submission of impermissible claims for reimbursement
- But suppose they are included in a medical compendium, states a claim under the FCA. Proof of falsity could entail a showing that a provider sought reimbursement for an off-label use, rather than a medically accepted use that was from a federal health care program or a use that was off-label and not covered by that program.

“Drugs” covered under Medicare Part B include any drugs or biologics used in an ambulatory surgical regimen for a medically accepted indication.” 42 U.S.C. § 1395x(t)(2)(A). United States ex rel. Fink v. Parke-Davis, 147 F.3d 1302, 1311 (9th Cir. 2000).

Carrier decisions subject to appeal. “Medically accepted indication” is defined to include:

“With the exception of claims that are properly coded and submitted to promote treatment in a medically accepted indication, a provider shall not submit a claim for reimbursement for a service or item that is not covered by the government health care program unless the provider can establish that the service or item is covered by the government health care program only for items and services that are covered:

- (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, peer-reviewed medical literature...”

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



New Government Theory of Liability: “Fraudulent” Claims

“The FCA’s structure is intended not to 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 the 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 and its scope should not be broadened to punish every type of fraud committed against the Government, for instance, where a claimant fails to comply with all applicable regulations. Government program seriously undermines this principle.”

United States ex rel. Riley v. St. Luke’s Episcopal Hospital, et al., 252 F.3d 749 (5th Cir.2001)

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



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



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 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

The relators speculate that a false claim must have been submitted to the government, arguing that “it is possible that a strong inference that physicians prescribed Genotropin from 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.”

Rule 9(b)

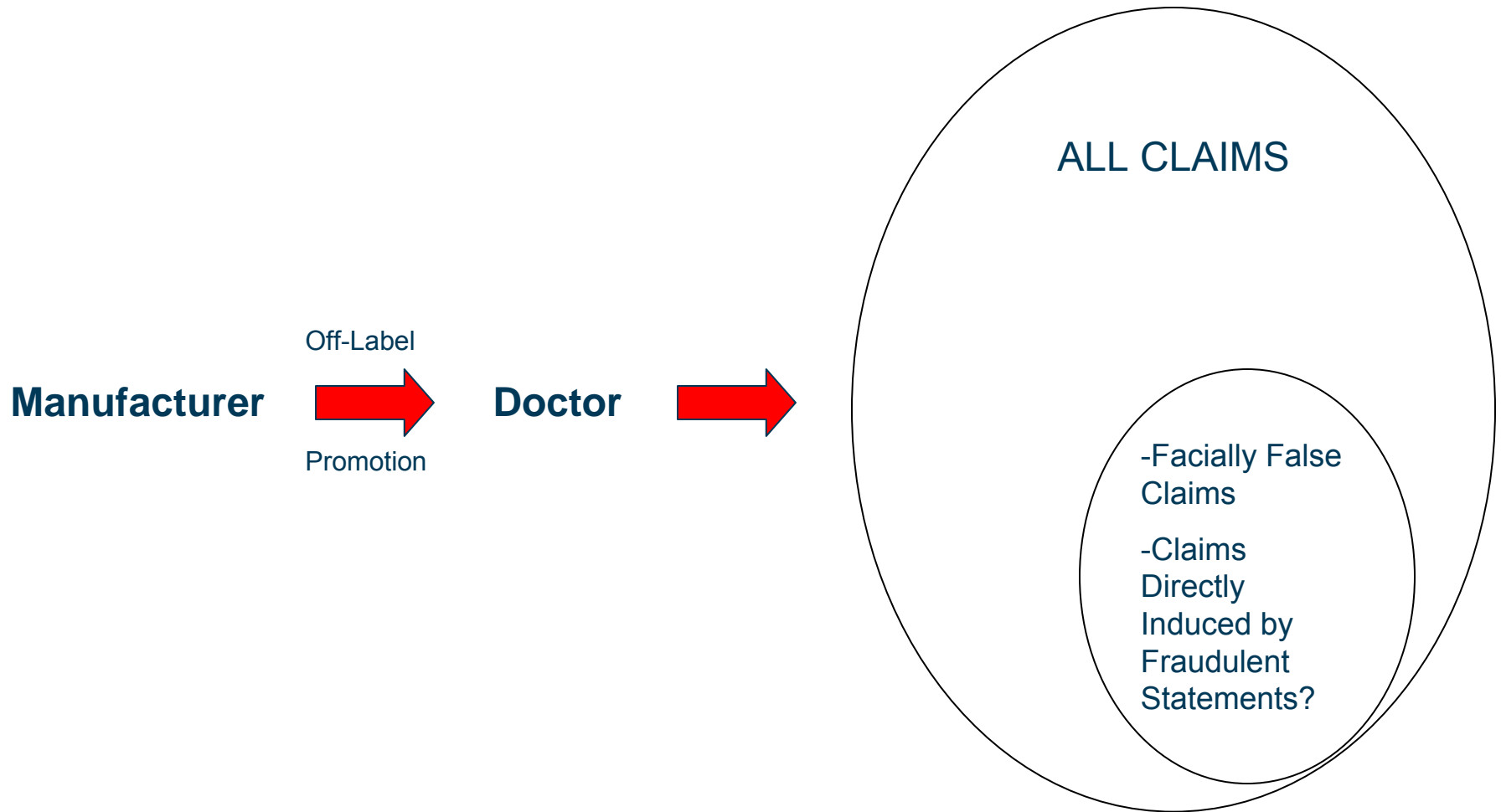
United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720 (1st Cir. 2007)
Hopper v. Solvay Pharmaceuticals, Inc., 2008 WL 4177927 (M.D. Fla. Sept. 8, 2008)

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



Who Will Prevail?



The End