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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

Washington, D.C.
October 28, 2008

Paul E. Kalb, M.D., J.D.

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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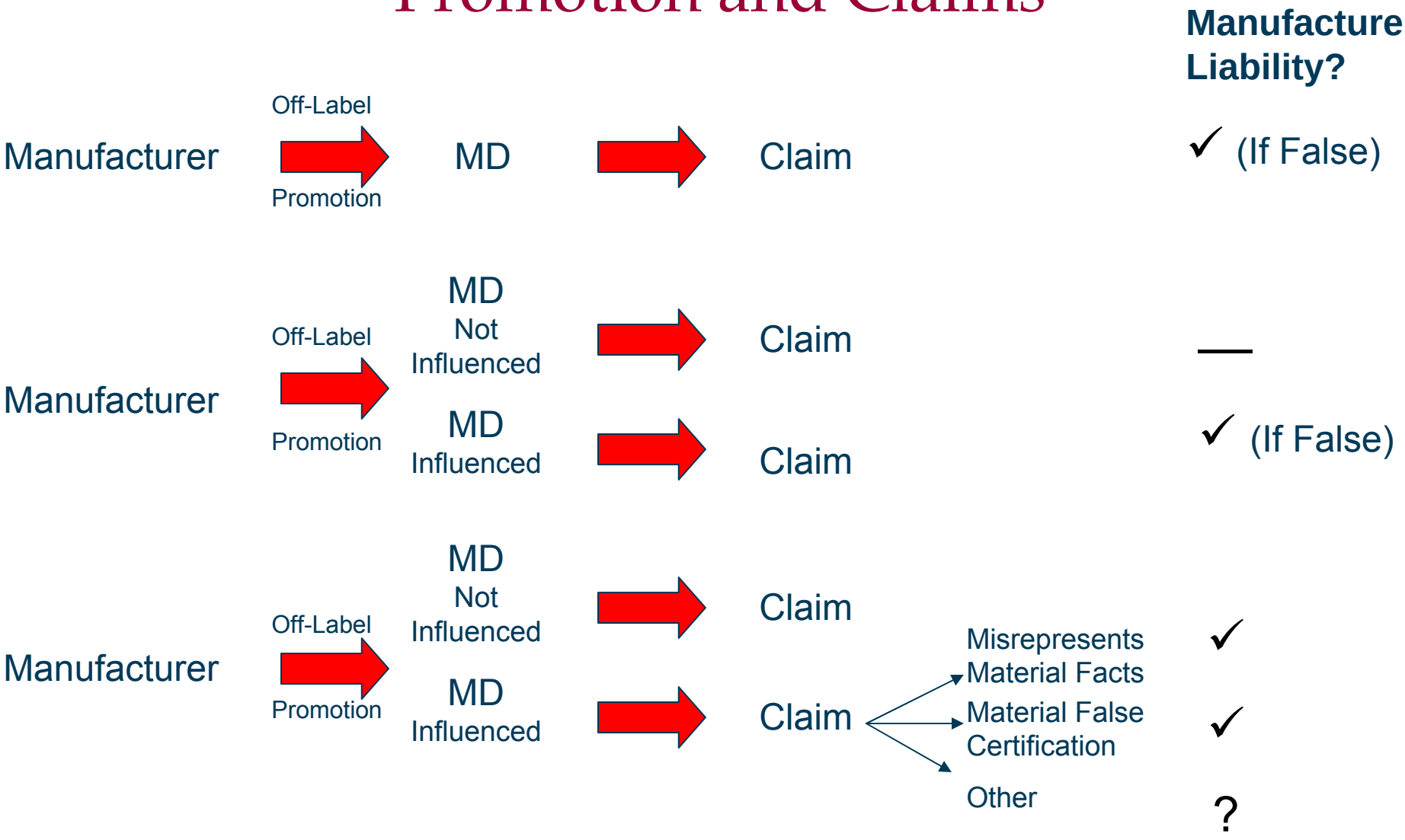
Promotion and Claims



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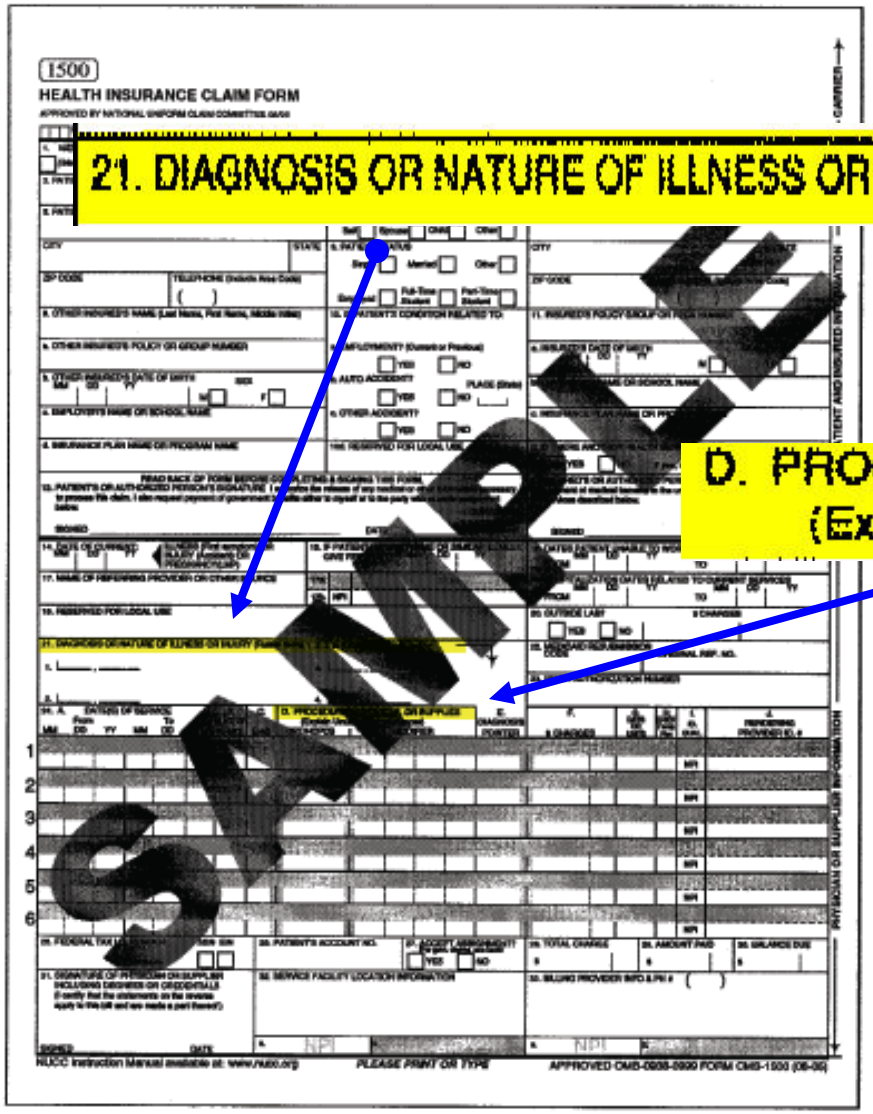
Factual Falsity?



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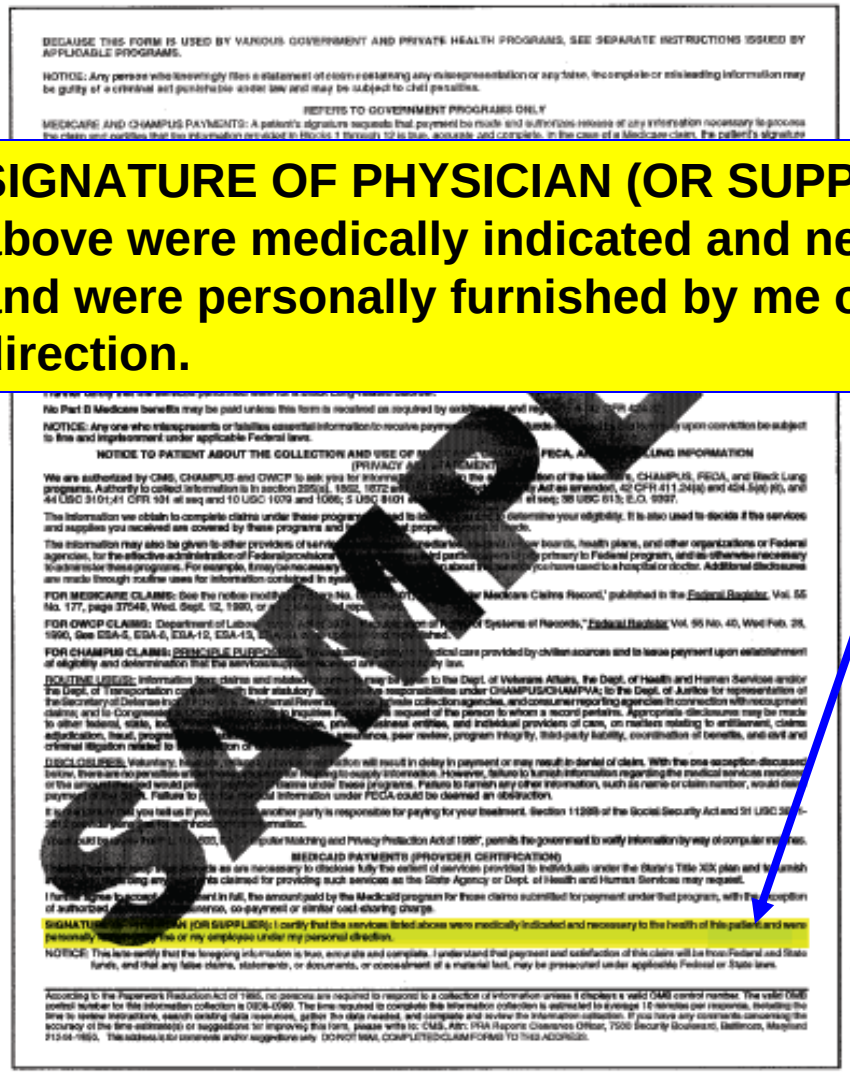
False Certification?



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 Blocks 1 through 12 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.

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

NOTICE: Any one who misrepresents or falsifies essential information to receive payment

to fine and imprisonment under applicable Federal laws.

NOTICE TO PATIENT ABOUT THE COLLECTION AND USE OF

We are authorized by CMS, CHAMPUS and OWCP to ask you for

The information we obtain to complete claims under these

and supplies you received are covered by these programs and

The information may also be given to other providers of

agencies, for the effective administration of Federal provisions

FOR MEDICARE CLAIMS:

FOR OWCP CLAIMS:

FOR CHAMPUS CLAIMS:

ROUTINE USES:

DISCLOSURES:

MEDICAID PAYMENTS (PROVIDER CERTIFICATION)

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?
  - Misstatement legally correct?
  - Liability only attaches to knowing submission of false claims
  - Reimbursement is often left to discretion of carriers
  - Providers have responsibility to determine whether reimbursable
  - Carrier decisions subject to appeal
- If proof of non-covered claim is not sufficient, then what?

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

Manufacturer Liability?

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' 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)

"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 would constitute a false claim."

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 anti-cancer 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 a patient has established 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)

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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)

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New Government Theory of Liability: "Fraudulent" 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."

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

"…The [illegible] fraudulent attempt 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)

"The facial accuracy of a claim 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.

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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

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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 that a strong demand for Marinol resulted 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."

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)

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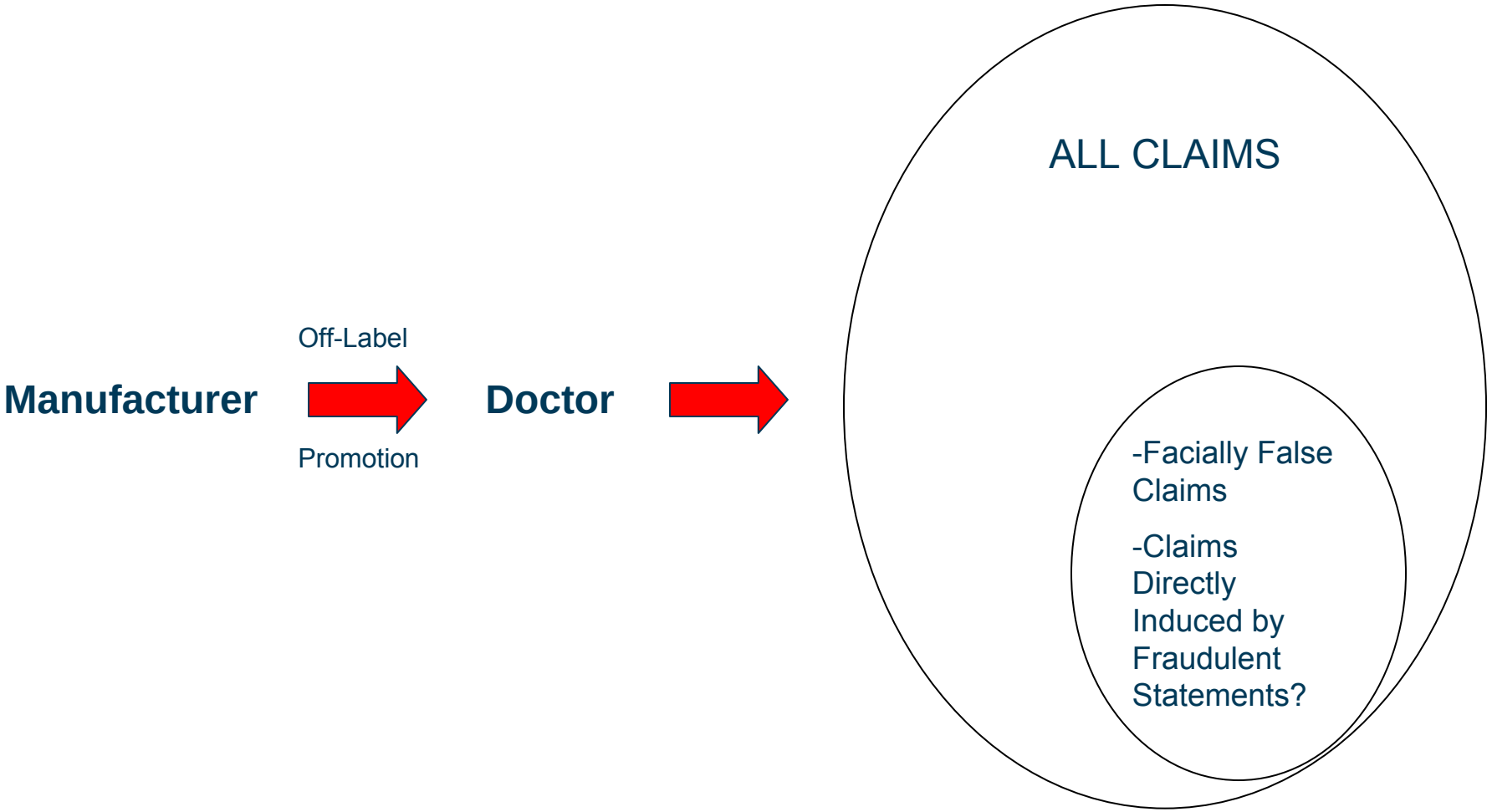
The Government v. The Defense



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Who Will Prevail?

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The End

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