



ALERT  
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## Sixth Circuit Reinforces "Stringent" Pleading Standard in False Claims Act Cases

The Sixth Circuit's recent decision in *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.* reinforced Federal Rule of Civil Procedure 9(b)'s requirement that plaintiffs plead fraud "with particularity" in False Claims Act cases. This "stringent" standard prevents broad, costly discovery in insufficiently pled FCA cases.

In *Ibanez*, former employees alleged that pharmaceutical companies encouraged providers to prescribe a drug for "off-label" uses. They alleged a four-step chain: (1) the defendants promoted the drug for off-label uses; (2) physicians thus prescribed the drug; (3) patients filled the prescriptions; and (4) pharmacies submitted claims to the government for reimbursement.

The Sixth Circuit affirmed dismissal of these claims for two reasons. First, the employees failed to allege with particularity a representative claim for payment. As courts throughout the country have repeatedly held, a False Claims Act claim may proceed only if a claim for payment is submitted; an allegedly fraudulent scheme is not enough. While the Sixth Circuit recognizes an exception at the pleading stage if a party has "specific personal knowledge" related to billing that supports "a strong inference that a false claim was submitted," the relators were sales representatives, not billers, so they lacked such knowledge. Second, although the employees tried to amend their complaint to add purported representative claims, no claim sufficiently described each link in the causal chain. Some claims, for example, failed to connect prescribing physicians to the defendants' promotion, or failed to show that prescriptions were for off-label uses.

Looking forward, other courts can use the Sixth Circuit's approach to apply Rule 9(b) to complex fraudulent schemes, particularly those with "a long chain of causal links." Critically, the complaint must "identify a representative false claim that was actually submitted to the government" and describe "each step" in the causal chain "with particularity." Merely describing certain elements of an alleged fraudulent scheme is insufficient.

The opinion also is notable because it emphasized "just what an awkward vehicle" the False Claims Act is "for punishing off-label promotion schemes." Without addressing the issue in detail, the court suggested that the False Claims Act may be the wrong tool to regulate off-label drug promotion, despite its repeated use by relators and the government.

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### CONTACTS



Stephen G. Sozio  
Cleveland



B. Kurt Copper  
Columbus

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