

## Fourth Circuit Holds False Claims Act Relators to Strict Pleading Standard: Ruling Will Be Particularly Useful in Defending Off-Label Promotion Cases

On January 11, 2013, the United States Court of Appeals for the Fourth Circuit issued an opinion reaffirming the requirement that False Claims Act relators plead presentment of a false claim with particularity. *United States ex rel. Nathan v. Takeda Pharmaceuticals N.A. Inc.* (No. 11-2077). The Fourth Circuit's decision requires relators proceeding under the civil False Claims Act, 31 U.S.C. Section 3729(a)(1)(A), to offer concrete details that plausibly allege—not just speculate—that actual presentment of a false claim occurred. By holding relators to the requirement of pleading false claims with particularity, the Fourth Circuit strikes a blow against relators who would simply allege a fraudulent scheme with hopes of basing the rest of their case on facts learned through costly discovery. The holding should be of particular utility to defendants in cases that are based on alleged “off-label” promotion, in which relators often rely on speculative assertions that claims were actually submitted for reimbursement for off-label uses that were ineligible for payment under government-funded programs.

In *Nathan*, a sales manager for Takeda Pharmaceuticals filed a *qui tam* suit alleging Takeda caused false claims for payment to be presented to the federal government by marketing the drug Kapidex for off-label uses. The relator identified two marketing practices he claimed resulted in false claims: (1) Takeda's promotion of Kapidex to rheumatologists, who do not typically treat patients with conditions that can be treated by Kapidex's on-label uses; and (2) Takeda's promotion of high doses of Kapidex for the treatment of conditions for which the FDA has approved only lower doses.

Liability under Section 3729(a)(1)(A) of the False Claims Act requires that the defendant actually presented a false claim to the government for payment. *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 789 (4th Cir. 1999). Relying on *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009), the relator in *Nathan* urged the Fourth Circuit to adopt a relaxed application of Rule 9(b)'s pleading standard that would permit the relator to plead only the existence of a “fraudulent scheme” from which the relator argued the court should infer that actual false claims for payment were presented to the government. In *Grubbs*, the relator had alleged a conspiracy by doctors in which doctors fraudulently recorded having performed medical services that were never actually performed. The Fifth Circuit held that the relator's presentment allegations satisfied Rule 9(b), even absent specific allegations that the doctors' fraudulent records caused the hospital's billing system to present fraudulent claims to the government. *Id.* at 192.

The Fourth Circuit rejected the relaxed standard urged by the relator. In doing so, it noted that the goals underlying Rule 9(b)'s heightened pleading standard—providing notice to defendants, preventing frivolous suits, eliminating fraud cases in which the facts are all learned in discovery, and protecting defendants from reputational harm—all apply with equal force in False Claims Act cases. Indeed, the court stressed, even under the general pleading standard articulated in *Iqbal*, relators must still offer “plausible allegations of presentment.” Op. at 8.

The court of appeals also distinguished *Grubbs* on its facts. In *Grubbs*, the Fourth Circuit explained, it would have defied logic to presume that the doctors would record services not performed, but then deviate from the normal billing track at the last moment to prevent those services from being billed. By contrast, allegations that suggest only that the defendant's actions “could have led but need not necessarily have led to the submission of false claims,” Op. at 10 (emphasis original), are insufficient to satisfy Rule 9(b).

The court went on to hold that the relator's allegations were insufficient. According to the court, while the relator offered general statistics that suggested off-label claims *may* have been presented to the federal government, the complaint never directly alleged facts giving rise to a plausible inference that any false claim was in fact submitted to the government for payment as a result of Takeda's marketing practices. For example, the relator alleged that Takeda's provision of 60 mg dose samples of Kapidex to 16 primary care physicians (PCPs) resulted in 98 prescriptions by those PCPs that were submitted to the government. The relator had further alleged that most physicians tend to prescribe the dose that was in the sample the physician received, that a 60 mg dose was approved only for a condition that PCPs generally do not treat, and that 93 percent of overall Kapidex sales were for dosages of 60 mg. Therefore, the relator reasoned, the court could infer that Takeda's off-label promotion resulted in the presentment of false claims. The Court rejected this chain of inferences. First, the complaint did not connect overall sales of Kapidex to the 98 prescriptions at issue. Indeed, the court explained that if PCPs do not treat the condition for which 60 mg Kapidex was approved, then it stood to reason that far fewer than 93 percent of PCP Kapidex prescriptions were at the 60 mg dose. The court further reasoned that, even if the relator could plausibly allege that all 98 prescriptions were written for 60 mg, it was still possible that they were written for approved uses. The court refused to infer from the relator's "general facts" that the particular prescriptions at issue had been for conditions, or doses, for which the government precluded payment. Op. at 13.

In *Nathan*, the Fourth Circuit reaffirms that relators do not adequately plead False Claims Act liability simply by alleging a "scheme" to market a drug for uses that are outside the scope of its approved labeling. The *sine qua non* of False Claims Act liability is a false claim. Stressing "the potential consequences flowing from allegations of fraud by companies who transact business with the government," Op. at 7, the Fourth Circuit rightly required relators to make specific allegations of the presentment of false claims, rather than allowing them to file first and then see if discovery yields evidence to support the suit.

If you would like further information, please contact the Ropes & Gray attorney who usually advises you.