



## HEALTHCARE/WHITE COLLAR UPDATE

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## Supreme Court Limits The Scope Of FCA Liability; Requires Intent To Cause The Government To Pay A Claim

On June 9, 2008, the Supreme Court issued an opinion in *Allison Engine Co. v. U.S. ex rel. Sanders*, No. 07-214, resolving a split among the Federal Courts of Appeal and significantly limiting the expansion of liability under the False Claims Act to entities that do not directly submit claims to the Government. This important decision, with implications for health care providers and pharmaceutical manufacturers in managed care transactions and other federal subcontractors, rejects the argument that a defendant may be held liable under sections 3729(a)(2) (false statements) and (3) (conspiracy) merely upon proof that a private entity paid a claim using funds received from the Government. The Supreme Court instead held that FCA liability is limited to acts done with an intent that the “Government itself” pay a false claim. Slip Op. at 5. The Court held that the contrary view — advocated by the United States — “impermissibly deviates from the statute’s language.” *Id.*

### A. Background

The *Sanders* relators alleged that three subcontractors that supplied electrical power generator sets (“Gen-Sets”) to shipyards with contracts to build missile destroyers for the U.S. Navy sought payment from the shipyards for Gen-Sets that did not satisfy contract specifications. Relators claimed that defendants knowingly falsely certified to the shipyards that the Gen-Sets met contract requirements in order to receive payment, in violation of the “false statements” and conspiracy provisions of the FCA, 31 U.S.C. § 3729(a)(2), (3). At trial, relators introduced the false certifications and invoices submitted by the subcontractors to the shipyards but did not introduce any invoices submitted by the shipyards to the U.S. Navy. The District Court granted a judgment as a matter of law to the defendants. No. 1-:95-cv-920, 2005 WL 713569 (S.D. Ohio, Mar. 11, 2005). Relying on the D.C. Circuit’s decision in *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004), the District Court held that

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relators' failure to prove that any claims were submitted to the Government was fatal to their FCA claims. *Id.*, at \*10.

The Sixth Circuit reversed, holding that unlike section 3729(a)(1) of the FCA, sections 3729(a)(2) and (a)(3) do not require, as an element of the claim, that a false claim be presented to the Government. 471 F.3d 610 (2006). The Sixth Circuit ruled that the subcontractors could be liable based upon proof that they intended to cause the shipyards to pay their claims with Government funds. The Supreme Court granted certiorari to address the conflict between the Sixth Circuit's holding and that of the D.C. Circuit in *Totten*.

## **B. The Decision**

The Supreme Court rejected the Sixth Circuit's holding that defendants could be liable under the sections 3729(a)(2) and (a)(3) of the FCA for false statements made to private entities. The Court held that such a result would be inconsistent with both the plain language and the purpose of the FCA. Examining the language of section 3729(a)(2), which prohibits making a false record or statement "to get" a false or fraudulent claim "paid . . . by the Government," the Court held that the section requires a showing that a defendant "intend[ed] that the Government itself pay the claim." Slip Op. at 5. Noting the FCA's "intended role of combating 'fraud against the Government,'" the Court reasoned that this element of intent is necessary to preserve the proper scope of the FCA. *Id.* In so doing, the Court expressly rejected the view that liability under section 3729(a)(2) may attach to any false statement that results in the distribution of federal funds. "Recognizing a cause of action under the FCA for fraud directed at private entities would threaten to transform the FCA into an all-purpose antifraud statute." Slip Op. at 9. Thus, FCA liability for false statements made by a subcontractor or other defendant to a private entity will attach only where the defendant "intend[s] the Government to rely on that false statement as a condition of payment." Slip Op. at 8. Similarly under section 3729(a)(3), the Court held that liability for conspiracy under the FCA requires a showing of intent that the false statement "would

have a material effect on the Government's decision to pay the false or fraudulent claim."

Although the Court held that it is "necessary for the defendant to intend that a claim be 'paid . . . by the Government' and not by another entity," it also rejected the argument, made by the subcontractor defendants, that section 3729(a)(2) requires proof that a false record or statement was presented to the Government. Rather, the Court held that a defendant may be liable under the FCA if it presents a false record or statement to a contractor, grantee, or other recipient of federal funds with the intent that the entity in turn use that record or statement to cause the Government to pay its claim. Slip Op. at 7-8.

## **C. Implications for FCA Claims Against Health Care Providers and Pharmaceutical Companies**

The Supreme Court's ruling in *Sanders* significantly narrows the scope of potential FCA liability. Under the Sixth Circuit's expansive reading of sections 3729(a)(2) and (3) of the FCA, health care providers that provided services on a capitated basis under contracts with private Medicaid managed care organizations could be liable under the FCA for false statements or certifications made to the MCO based solely on the fact that the MCO received federal funds. Similarly, the Sixth Circuit's interpretation would have made pharmaceutical manufacturers subject to FCA claims on the theory that their promotional activities were intended to cause pharmacists or physicians to dispense products for which claims were paid with federal funds by a Medicaid MCO or Medicare Part C organization or Part D plan. Under the *Sanders* ruling, however, statements made by health care providers to a private entity regarding particular services or products will not give rise to liability absent proof that the statements were made with the intent of causing "the Government itself" to "pay the claim." Slip Op. at 5.

The ruling also calls into doubt the Federal Government's theory — recently reaffirmed in its Statement of Interest filed in *United States ex rel. Rost v. Pfizer*, 03-CV-11084 (D. Mass. May 12, 2008) — that off-label promotion by pharmaceutical

manufacturers may give rise to liability under section 3729(a)(2). The Government argues that “a statement urging a physician to prescribe a drug for a unapproved, off-label use could . . . satisfy the false statement requirement of section (a)(2).” *Id.* at 9. Notwithstanding whether such a statement would be “false,” the Court’s holding in *Sanders* indicates that such a statement may not give rise to FCA liability unless the Government proves that it was made with the requisite intent that the Government rely on that statement as a condition of payment. Slip Op. at 8. Unless the Government makes such a showing, “the direct link between the false statement and the Government’s decision to pay or approve a false claim is too attenuated to establish liability.” *Id.*

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