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Supreme Court's *Mens Rea* Decision in Drug Case May Have Significant Implications for False Claims Act Cases Based on Anti-Kickback Violations

On June 27, in *Ruan v. United States*, the U.S. Supreme Court held that the *mens rea* necessary to support a Controlled Substances Act (CSA) violation also applies to the affirmative defense. Inasmuch as the sentence at issue in the CSA is syntactically similar to the operative sentences in the federal Anti-Kickback Statute (AKS), the case may have wide-reaching implications for False Claims Act (FCA) cases based on an AKS violation.[1]

In *Ruan*, two physicians were separately convicted of violating a CSA provision that makes it unlawful, "[e]xcept as authorized[,] . . . for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance." 21 U.S.C. § 841. Each of the physicians argued that they lawfully dispensed the opioids because they were dispensed pursuant to valid prescriptions. A regulation provides that, "to be effective," a prescription "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR § 1306.04(a). One of the doctors argued that whether he met this standard should be judged by his subjective intent. The trial court instead set forth a more objective standard, instructing the jury that a doctor acts lawfully when he prescribes "in good faith as part of his medical treatment of a patient in accordance with the standard of

[1] Under the Social Security Act, a violation of the AKS, even if not criminally prosecuted, can form the basis of a civil False Claims Act case. See Social Security Act § 1128B(g).

medical practice generally recognized and accepted in the United States." With respect to the other doctor, the trial court instructed the jury, also using an objective standard, that to take advantage of the affirmative defense, the defendant must have "acted in an honest effort to prescribe for patients' medical conditions in accordance with generally recognized and accepted standards of practice." Slip Op. at 4. Both doctors were convicted, and the convictions were affirmed on appeal, one in the Eleventh Circuit and the other in the Tenth Circuit.

The Supreme Court reversed both convictions, holding that the "knowingly or intentionally" *mens rea* clause applies to the "except as authorized" clause, as well as to the remainder of the provision. It reasoned that a scienter provision in one portion of a criminal statute is presumed to apply to the entire provision, even though one of the clauses sets forth an affirmative defense while the remainder of the provision spells out the elements of the crime. The Court rejected the government's argument that the *mens rea* presumption should not apply to those portions that involve the affirmative defense.

Justice Alito, in his concurring opinion, highlighted the implications of the Court's reasoning:

> In criminal law, the distinction between the elements of an offense and an affirmative defense is well-known and important. In these cases, however, the Court recognizes a new hybrid that has some characteristics of an element and some characteristics of an affirmative defense. The consequences of this innovation are hard to foresee, but the result may well be confusion and disruption. That risk is entirely unnecessary.

The AKS statute, like the CSA provision at issue in *Ruan*, sets forth the elements of the crime at Social Security Act § 1128B(b)(1) & (2), but then goes on to state that it "shall not apply to . . .

> a discount or other reduction in price obtained by a provider of services or other entity under title XVIII or a State health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under title XVIII or a State health care program

Social Security Act § 1128B(b)(3)(A).

Under the *Ruan* reasoning, the AKS's "knowingly and willfully" scienter requirement would apply to the exception at subparagraph (A), no matter how one characterizes that exception, e.g., as an affirmative defense, an element of the crime, or a hybrid. Thus, a plaintiff would have to prove that the offeror knew that the discount would not be reported; this may be a difficult hurdle for most relators to overcome. And, *Ruan* arguably imposes a higher standard of proof in AKS-based FCA cases where the defendant is invoking a statutory exception to liability, thereby making it more difficult for relators in the civil setting and prosecutors in the criminal setting.

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