CLIENT ALERT

Another Win for Reasonableness

August 21, 2018

There are none more regulated than those who receive funds directly from the government, including federally subsidized healthcare providers. It is no surprise, therefore, that the government and *qui tam* relators constantly push the boundaries of what "violates" applicable regulations and, they argue, the False Claims Act, 31 U.S.C. § 3729 *et seq.* (FCA).

A recent decision from the Third Circuit reinforces the proposition that a reasonable interpretation of regulations cannot result in knowingly false claims. *See United States v. Allergan, Inc.*, -- Fed. App'x --, 2018 WL 3949031 (3d Cir. Aug. 16, 2018).

A. The regime at issue

Drug manufacturers sell their products to wholesalers. Those wholesalers pay a price for the drugs, of course, but also charge a "service fee" to the manufacturers. Some wholesalers engage in "speculative buying," in which they stockpile drugs when their price is low and sell them later when the price rises. To counteract this practice, manufacturers began demanding "price-appreciation credits" in the form of discounts from the service fees. Thus, strictly speaking, these credits did not affect the price of the drugs—they were paid through a different mechanism.

The *Allergan* case revolved around how to calculate the Average Manufacturer's Price (AMP) paid by the wholesalers. The AMP matters because, under the Medicaid Drug Rebate Program (MDRP), the manufacturers pay a rebate to the states in proportion to the AMP. The lower the AMP, the lower the rebates. The applicable law, 42 U.S.C. § 1396r-8(k)(1), went through three iterations during the timeframe relevant to the case. None of those iterations spoke directly to the question of the "price-appreciation credits" had to be accounted for as the manufacturers calculated the AMP.

B. Analysis under the FCA

The *Allergan* decision builds upon a burgeoning strand in FCA jurisprudence, perhaps most clearly articulated in *United States ex rel. Purcell v. MWI Corporation*, 807 F.3d 281, 287-88 (D.C. Cir. 2015): the FCA does not "reach those claims made based on reasonable but erroneous interpretations of a defendant's legal obligations."[1]

The analysis under *MWI* and related decisions proceeds in three parts: (1) whether the relevant statute was ambiguous; (2) whether a defendant's interpretation of that ambiguity was objectively unreasonable; and (3) whether a defendant was "warned away" from that interpretation by available administrative and judicial guidance. *Allergan*, 2018 WL 3949031, at *3 (citing *MWI*, 807 F.3d at 288).

C. Applied to *Allergan*

The court found that the applicable statute did not "unambiguously require[] price-appreciation credits to be added to the price paid by wholesalers." *Id.* at *4. The statute was thus ambiguous, and "could be read as referring to the price initially paid to the manufacturer by the wholesaler," not some 'adjusted' price reflecting the price-appreciation credits refunded through the service fees. *Id.* at *5. Finally, there was nothing to warn the defendants away from that interpretation.

Indeed, the record showed the relevant agencies playing hot potato with the issue. A 2006 Health & Human Services (HHS) Office of Inspector General (OIG) Report recommended that HHS "consider addressing issues raised by industry groups, such as: administrative and service fees." *Id.* In its comments, however, the Centers for Medicare and Medicaid Services (CMS) said it "had hoped that the OIG would have provided more specific recommendations for us to consider as we develop a proposed rule to address this topic." *Id.* Both sides sat on their hands, hoping the other would go first.

In 2012, CMS *proposed* a rule that said price-appreciation credits were "*likely* not excludable from AMP." *Id.* (emphasis added). But by the time the agency cemented that position in 2016, the alleged conduct in *Allergan* had passed.

[1] One of our co-authors, Mr. Lynch, was a member of both the trial and appellate team in the *MWI* case, which successfully obtained a reversal of the jury's finding of liability on appeal.

D. Conclusion

The *Allergan* defendants reasonably interpreted an ambiguous provision. While it should not take a body of appellate caselaw to support the commonsense proposition that such actions are not fraudulent, that caselaw *is* developing. We will continue to monitor those developments.

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