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Par Pharmaceutical Beats FCA Prescription-Switch Allegations

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In the fourth of a related set of *qui tam* False Claims Act (FCA) suits, the United States District Court for the Northern District of Illinois granted summary judgment in favor of generics manufacturer Par Pharmaceutical Companies (Par). The court's August 17, 2017, opinion in *U.S. ex rel. Lisitza et al v. Par Pharmaceutical Co, Inc.* held that the relator had not presented sufficient evidence to support an implied certification theory of FCA liability.

Like its sister cases, the relator in *Par Pharmaceutical* alleged that the defendant caused the submission of false claims to the Medicaid program via an unlawful prescription-switching scheme. The alleged scheme involved manufacturing generic drugs in forms and dosage strengths that were atypical and not covered by existing Medicaid reimbursement limits, then marketing the drugs to pharmacies based on their higher reimbursement potential. The pharmacies would then fill the scripts with the more expensive forms and dosages manufactured by Par. The relators also alleged that the drugs were dispensed without physician approval and without meeting the medical necessity and economic requirements of governing state and federal Medicaid regulations, in violation of the FCA.

Par moved for summary judgement on the grounds that the relators cannot prove that the pharmacies submitted any "false" claim for reimbursement based on their dispensing any of Par's drugs, failing to satisfy the FCA's falsity requirement. The relators asserted multiple, purported theories of FCA liability. Among other things, they maintained that the reimbursement claims for these Par products were "inherently" false because the Medicaid programs were being "overcharged," putting forth a theory of strict liability on the premise that charging the government anything but the lowest possible rate was inherently a false claim. The court found that this "inherent" falsity argument would "read[] the requirement of a false or misleading statement out of the [FCA]." Along the same lines, the court pointed out that omissions on the claim itself about the course of events leading to the dispensing of a particular drug, or about the relative cost of that drug, do not "go to the truth or falsity of the representations on the claim for itself."

The court also rejected another of relators' proffered theories—that liability arises whenever there is a "direct nexus" between a fraudulent scheme and inflated payments—as inconsistent with the US Supreme Court's decision in *Universal Health Services, Inc. v. United States ex rel Escobar* (with the court reiterating the Supreme Court's admonition that the FCA is not "an all-purpose antifraud

statute" and that liability must be tied to a false claim). The *Par* court found no support in controlling precedent for this "direct nexus" theory, and ultimately observed that the relators "consistently framed their claims in a way that cannot be meaningfully differentiated from the implied false certification theory."

The relators argued that their claim survives even under an implied false certification theory. In *Escobar*, the Supreme Court held that implied certification can be a basis for liability when the claim for payment makes specific representations about the goods or services provided and the defendant's failure to disclose noncompliance with material legal obligations makes those representations "misleading half-truths." The relators contended that the claims had NDC numbers ("specific representations") and contained misleading half-truths because they omitted information regarding the originally prescribed drug and pricing information as well as Par's switching scheme, with such omissions rendering the claim misleading. The court was unpersuaded, finding that the relators had not identified with precision any "specific representation" as required by *Escobar,* nor any omitted information that rendered the description of the dispensed drugs a misleading half-truth. The court agreed with Par that the pharmacies' claims did not falsely imply incorrect information regarding the goods provided, and that the claims were not misleading because they failed to include extraneous information regarding drug pricing, the original prescription or Par's alleged switching scheme.

This holding is significant because some courts have diverged with respect to whether *Escobar's* "specific representation" requirement is mandatory. *Par* confirms that it is indeed mandatory, a result consistent with the Supreme Court's *Escobar* opinion.

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