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FCA Liability After Escobar: Challenges And Opportunities For Device Companies

A RECENT SUPREME COURT DECISION ADDRESSING the False Claims Act holds important implications for medical device companies, according to Gibson Dunn attorneys John D. W. Partridge, Jonathan M. Phillips and Reid F. Rector in this guest column.

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The federal False Claims Act (FCA) is the government's primary tool for policing alleged health-care fraud and abuse. For many medical device companies, the risks and costs associated with the FCA are all too familiar: recent years have seen a steady stream of blockbuster FCA lawsuits and hefty recoveries from device companies.

But a recent Supreme Court decision on the FCA may have a significant impact on how courts apply the statute in cases against device manufacturers. In June, the court decided *Universal Health Services Inc. v. United States ex rel. Escobar* (136 S. Ct. 1989, 1997 [2016]), a case testing the validity of a theory of FCA liability known as "implied certification." That theory is one that the government and private whistleblowers, who may bring suit on the government's behalf, have relied on heavily in recent years to exact huge settlements or sanctions for alleged violations of health-care regulations. The court concluded that a company can be liable (at least in some circumstances) for submitting a claim for government reimbursement that falsely *implies* that the company has complied with an important statutory, regulatory, or contractual requirement. For medical device companies, which are subject to numerous complex and ever-evolving legal requirements, the Escobarcourt'sratification of FCA liability based on representations relating to regulatory requirements has potentially far-reaching consequences.

In this article, we summarize Escobar's teachings and then consider the key legal arguments for device companies in the post-Escobar era, focusing on FCA cases alleging "off-label" promotion, violations of Medical Device Reporting (MDR) and Quality System Regulation (QSR) requirements, and kickbacks. We also address the government health program reimbursement framework for medical devices, which may provide some ammunition for device companies to challenge the government's or whistleblowers' efforts to impose expansive FCA liability.

The Escobar Decision

Escobar involved allegations that a mental health hospital provided inadequate care to a teenage patient by using counselors whose qualifications did not meet regulatory requirements. The patient's parents filed suit under the FCA alleging that the hospital submitted false claims for payment by Medicaid by "impliedly certifying" that the services were provided by specific types of professionals (in accordance with state regulations), when in fact, they were not.

Before Escobar, some lower courts relied on the "implied certification" theory to hold that claims for payment could be false or misleading, even if they said *nothing* about a defendant's compliance with underlying laws, rules or regulations. The Supreme Court did not go that far. Rather, the court held that the implied false certification theory can provide a basis for liability under the FCA "at least" where (1) a "claim does not merely request payment, but also makes *specific representations about the goods or services provided,*" and (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations *misleading half-truths*." (Emphasis added.)

The court did not stop there. It also required that "a misrepresentation about compliance with a statutory, regu-

Key Takeaways

- Escobar is one of the most significant Supreme Court decisions on the False Claims Act in decades, with broad implications for medical device companies' risk and liability.
- The legal theory at issue in Escobar – implied false certification – is often used to target medical device companies – and the Supreme Court concluded that the theory is viable, at least in certain circumstances.
- But device companies are uniquely situated to use some helpful aspects of the Escobar opinion to argue against FCA liability in some cases.

latory, or contractual requirement must be *material* to the government's payment decision." The court rejected the notion that materiality hinges on whether a statutory, regulatory, or contractual requirement is expressly identified as a "condition of payment." According to the court, such labels are relevant to, but not dispositive of, the issue of *materiality* – that is, whether the misrepresentation would be important to the government's decision to reimburse the services in question.

The Supreme Court's recent decision returns the focus of the FCA to fraud, as informed by common law principles of fraud.

The court then dug into the FCA's "rigorous" materiality requirement, explaining "how [it] should be enforced." The relevant question is not merely whether the alleged underlying legal violation allows the government the *option* to deny payment, but whether the government actually would not have reimbursed the claims if it knew that it was billed for services performed in violation of the statute or regulation at issue. Courts applying the standard must assess whether the defendant's noncompliance with the requirement, if disclosed, would have affected either a reasonable person's decision or the actual, subjective decision of the government agent. But, in any event, materiality "cannot be found where noncompliance is minor or insubstantial."

What Escobar Means For Medical Device Companies

Because medical device companies typically do not seek reimbursement of their products directly from government health programs, the government and whistleblowers tend to allege that device companies are liable under the FCA for *causing* another entity – e.g., a health-care provider that prescribes a device – to submit false claims. In many – if not most – cases, the government and whistleblowers contend that the provider's claim is false because of a "certification" of compliance with some regulatory, statutory or contractual obligation. That means that Escobar's "implied certification" liability implicates a host of FCA claims against device companies.

Medical device companies often face theories of FCA liability based on "implied certifications" that are particularly vulnerable after Escobar.

So what type of requirements give rise to the type of alleged "certifications" in cases against medical device companies? According to the government and whistleblowers in the most common types of FCA suits, providers certify that (1) the device is reimbursable for a specific use, which may be an issue if the device is used for an off-label purpose, (2) the device company complied with various regulatory requirements (e.g., MDR or QSR requirements), and (3) a claim for reimbursement was not the result of an illegal kickback.

Off-Label Promotion

Medicare regulations do not categorically bar reimbursement of devices supplied for off-label use, but rather limit reimbursement to cases where the device is "reasonable and necessary." FCA complaints against device manufacturers often try to thread the needle and allege that claims for off-label uses are false because the device was not FDA-approved, or reasonable and necessary, for that specific use, and therefore that the device company *caused* improper reimbursement

claims by promoting the device for such uses.

After Escobar, FCA plaintiffs proceeding on off-label theories may have to show, somehow, that the "specific representations" in claims for reimbursement for the device in question were either facially false or that they were rendered misleading by some material omission. This will be particularly challenging where providers seek reimbursement under a diagnosis-related group (DRG) code for a bundle of services and items (including the device) involved in a particular patient's treatment.

Indeed, by and large, claims for payment for a device – whether as part of a DRG or otherwise – contain only true statements about the device used and the patient's condition (even if that condition is not an approved indication). As a result, FCA plaintiffs should have a difficult time proving a "half-truth" in the claim, especially because the government typically knows – or should know – from the codes submitted that the device is being used off-label when it pays the claim. This disclosure to the government also may cause FCA plaintiffs to struggle to show that omissions regarding marketing are material – indeed, some courts had already begun to reject that argument. Further, defendants will continue to challenge whether an off-label use of a device is material when reimbursement for the device is sought as part of a DRG rather than for the device alone.

ABOUT THE AUTHORS

John D. W. Partridge, a partner at Gibson Dunn, focuses on internal investigations, regulatory inquiries, corporate compliance programs, and complex commercial litigation. He has particular experience with the FCA, and he has represented clients in criminal and civil enforcement actions relating to alleged health-care fraud and abuse. His substantive experience includes cases involving allegations relating to, among other issues, clinical trials, sampling practices, off-label promotion and anti-kickback laws.

Jonathan M. Phillips is a senior associate in Gibson Dunn's FDA and Health Care practice group, and a former trial attorney in the U.S. Department of Justice's Civil Fraud section. His practice includes counseling health care and life sciences clients in a range of government investigations and enforcement actions.

Reid F. Rector is an associate at Gibson Dunn, where he practices in the Litigation Department. He is a member of the firm's FDA and Health Care practice group and regularly represents clients in health-care fraud and abuse investigations and litigation, including in cases under the FCA and anti-kickback laws.

QSR, MDR Regulatory Violations

At first glance, Escobar's endorsement of FCA liability for regulatory violations is eye-opening for device-makers, given the many FDA regulations that pertain to medical devices. But, on closer examination, Escobar seems to have ratified prior courts' efforts to rein in such far-reaching theories.

Let's consider two important areas for medical device companies as examples. In both, courts have refused to recognize FCA liability based on alleged violations of adverse-event reporting and manufacturing quality regulations. Escobar reinforces those decisions.

First, in a case with clear parallels to MDR compliance cases, a federal court rejected a whistleblower's allegation that a pharmaceutical manufacturer defrauded the government by failing to comply with adverse event reporting (AER) requirements (*United States ex rel. Ge v. Takeda Pharmaceutical Co. Ltd.* [D. Mass. 2012]). According to the court, AER compliance was not a "material

precondition of payment" because FDA exercises enforcement discretion in that area and the whistleblower had not shown that FDA would have withdrawn approval for the drugs because of the alleged compliance issues. Although Escobar refused to base FCA liability on whether a regulation is an express "precondition of payment," the Supreme Court confirmed the high bar set by the Ge case for establishing materiality, especially given FDA's enforcement discretion. After Escobar, FCA plaintiffs cannot just say that the regulatory requirement at issue *could* have led to nonpayment of a medical device; they must establish with evidence that the government *would have* refused to pay based on the alleged noncompliance.

Second, in a case of particular interest to device companies because of their QSR obligations, a federal court refused to recognize a theory of fraud liability based on a defendant's alleged failure to comply with Good Manufacturing Practice (GMP) rules (*United States ex rel. Campie v. Gilead Sciences, Inc.* [N.D. Cal. 2015]). In the Campie case, the whistleblowers alleged that a drug manufacturer falsely promised FDA that it would comply with manufacturing regulations, particularly FDA's GMP provisions, and then fraudulently sought government reimbursement while failing to comply with those rules. The Campie court rejected those allegations, observing that the FCA was not meant as a "sweeping mechanism to promote regulatory compliance." The court concluded that the whistleblowers' theory was not viable because there was no representation of compliance to CMS – as opposed to FDA – in the course of requesting payment. By focusing on material "specific representations" about the products in question as part of the claim for government payment, Escobar appears to have confirmed the crucial distinction in Campie between representations of compliance made to *FDA* and representations made to CMS. Representations to FDA are an important compliance issue, of course, but Escobar indicates that they do not amount to a violation of the FCA. Whistleblowers alleging fraud based on QSR noncompliance should face an uphill climb after Escobar.

Anti-Kickback Statute

Another major theory of liability under the FCA for medical device companies focuses on purported violations of the Anti-Kickback Statute (AKS). Sales representatives and marketing personnel at device companies should be familiar with the AKS and its broad prohibitions against offering or paying any "remuneration" to induce providers to use a company's devices. Because the government interprets "remuneration" expansively, AKS cases can be premised on a broad array of arrangements between device companies and providers – from the obvious (cash payments and luxury vacations) to the not-so-obvious (speaking fees, consulting arrangements, patient care information and educational materials).

After the enactment of Patient Protection and Affordable Care Act, a medical claim that results from a violation of the AKS is false for purposes of the FCA. For cases based on conduct after the Act's effective date, the Escobar decision may not offer much in the way of new arguments.

But in FCA cases arising from alleged misconduct before 2010 – and there are still *plenty* lingering in the court system – plaintiffs must establish that claims obtained through kickbacks were false because the provider *certified* compliance with the AKS. To the extent that Escobar limits certification liability to cases where there is a "half-truth" made about the "services or goods provided," it is hard to see how pre-Affordable Care Act kickback cases can move forward.

Strengthened Arguments For Future Cases

In conclusion, Escobar provides device companies with unique new arguments to level against new and pending FCA lawsuits. Although FCA exposure will remain a major risk, companies can—and should—think about ways to fight back against meritless FCA suits using the arguments newly strengthened by the Supreme Court.

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