Crowell

CLIENT ALERT

DOJ Moves to Dismiss Ten Kickback-Related False Claims Act Complaints Against Pharmaceutical Companies

December 21, 2018

On Monday, DOJ moved to dismiss ten kickback-related FCA complaints against thirty-eight major pharmaceuticals companies and commercial-outsourcing vendors. The number of motions is striking in itself, because DOJ has rarely used that authority in the past, moving to dismiss approximately thirty FCA cases from 1986 to 2011. Monday's filings reinforce a trend of increased dismissals since the Granston Memo. And they follow on the heels of a high-profile announcement that DOJ is prepared to seek dismissal in *Gilead Sciences, Inc. v. United States ex rel. Campie*, on which we reported here. The motions demonstrate that the Granston Memo has teeth and suggest a narrower interpretation of the Anti-Kickback Statute that may offer some relief to the pharmaceutical industry, which has long been a primary target of FCA enforcement.

According to DOJ, the relators in all ten cases—and in an eleventh case voluntarily dismissed in July—are "shell" companies affiliated with the National Health Care Analysis Group, an LLC formed by three other LLCs and a limited partnership "solely to file *qui tam* actions." That would make the NHCA Group part of a growing number of repeat corporate relators that also includes Integra Med Analytics, a company that has filed several *qui tams* based on statistical analysis of CMS data. Integra has described itself in pleadings "as specializing in the use of statistical analysis to uncover and prove fraud."

Echoing the Granston Memo's warning against windfalls for opportunistic relators that provide no useful information, DOJ expressed concern that these professional relators lacked inside knowledge of the pharmaceutical industry and made "sweeping allegations" based on information that they obtained "under false pretenses." DOJ claimed that the NHCA Group obtained its information by posing as a neutral healthcare research company and tricking medical professionals into participating in a purported study on the effectiveness of the pharmaceutical industry's "investment" in nurse educators. The NHCA Group's affiliates then named the participants in the purported study as cooperating witnesses in FCA lawsuits alleging that the defendants violated the Anti-Kickback Statute by engaging in "white-coat marketing" and by providing free nurse and reimbursement-support services. According to DOJ, the NHCA Group's conduct was similar to that of another *qui tam* relator whose "fictitious research study" violated rules of professional conduct and prompted a federal district court in Massachusetts to dismiss a complaint last year.

DOJ asserted that the relators' kickback allegations "conflict with important policy and enforcement prerogatives." DOJ invoked the Granston Memo's concern that *qui tam* litigation could interfere with federal policy and argued that dismissal would protect rules allowing conduct that helps the beneficiaries of federal healthcare programs. To illustrate this point, it noted the relators' allegation that providing educational information and instruction for patients violated the Anti-Kickback Statute. According to DOJ, "HHS-OIG has advised that the provision of educational materials or informational programs to patients, without more, does not constitute 'remuneration'" under the statute. *See* 81 Fed. Reg. 88368, 88396 (Dec. 7, 2016). DOJ explained that HHS-OIG's advice reflects a significant policy interest in patient "access to basic product support relating to their medication, such as access to a toll-free patient-assistance line or instructions on how to properly inject or store their medication." And it cautioned that "relators should not be permitted to indiscriminately advance claims on behalf of the government against an entire industry

that would undermine common industry practices the federal government has determined are, in this particular case, appropriate and beneficial to federal healthcare programs and their beneficiaries."

The eleven complaints filed by the NHCA Group's affiliates covered a six-year period, involved three federal healthcare programs, and "implicate[d] more than 73 million prescriptions written by hundreds of thousands of different physicians for millions of different Medicare beneficiaries" under Medicare Part D alone. Consistent with the Granston Memo's aim of curbing meritless *qui tams*, DOJ noted that its "extensive investigation" of the complaints showed them to "lack sufficient factual and legal support." DOJ provided more detail about its investigation than in prior motions to dismiss, perhaps in response to a Northern District of California decision in June that denied a motion to dismiss based on DOJ's perceived failure to conduct a full investigation. *See United States v. Acad. Mortg. Corp.*, No. 16-CV-02120, 2018 WL 3208157 (N.D. Cal. June 29, 2018). DOJ has filed an appeal, which is pending in the Ninth Circuit.

DOJ noted that, in addition to conducting an extensive review of information provided by relators' counsel, it had collected and reviewed tens of thousands of documents from the defendants and from third parties, interviewed prescribing physicians and other witnesses, and consulted with subject-matter experts at HHS-OIG. DOJ explained that the Civil Division's Fraud Section alone spent over 1,500 hours on the investigation. Numerous Assistant U.S. Attorneys, HHS-OIG attorneys, law-enforcement agents, investigators, and auditors spent additional time evaluating the complaints.

DOJ argued that allowing the litigation to go forward would place additional and unjustified burdens on the government, especially because these burdens would divert resources from more meritorious matters. Like the Granston Memo and the Solicitor General's brief in *Gilead*, DOJ's motions noted the cost of monitoring litigation and responding to discovery requests involving "voluminous prescription drug event data and patient health information for potentially thousands of beneficiaries, which, due to its sensitive nature, may require additional (and costly) screening and redaction." DOJ also noted that the litigation would likely require the government to file "statements of interest relating to a variety of legal issues, including the potential need to address Relator's interpretation of the [Anti-Kickback Statute], statutory safe harbors, and HHS-OIG Advisory Opinions."

In addition to litigation burdens, DOJ expressed concern about burdens on the courts, the defendants, and third-party healthcare providers "who are not named as defendants but may get dragged into the case[s] by one or both parties." These concerns are consistent with public statements by Deputy Associate Attorney General Stephen Cox, who emphasized the importance of exercising the DOJ's dismissal authority to avoid "obvious" and "substantial" costs to defendants as well as to the government, as we noted here in an article discussing a circuit split on the degree of deference owed to DOJ motions to dismiss under 31 U.S.C. § 3730(c)(2)(A). They also reinforce remarks by then-Acting Associate Attorney General Jesse Panuccio, who noted that meritless *qui tam* actions "impose substantial costs on defendants and the judiciary" in a speech on FCA enforcement reform that we covered here and here.

Monday's motions to dismiss contain more detail than some prior motions and invoke a greater number of Granston Memo factors, shedding additional light on DOJ's approach to dismissals. Importantly, the relators brought claims on behalf of thirty-one states and the District of Columbia under their respective state false claims statutes. With the exception of New Jersey, every state consented to the DOJ's motion to dismiss, so long as it was without prejudice to the states. New Jersey took no position on the motions. We will continue to monitor developments in this area of increasing importance to FCA defendants.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

Keith J. Harrison
Partner – Washington, D.C.
Phone: +1.202.624.2560
Email: kharrison@crowell.com

David W. O'Brien
Retired Partner – Washington, D.C.
Phone: +1.703.307.1977
Email: dobrien@crowellretiredpartners.com