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DOJ As Your Ally: Government Weighs In on Patient Support Services Kickback Claims

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On December 17, the U.S. Department of Justice, in an unprecedented application of its statutory authority under section 3730(c)(2)(A) of the False Claims Act, moved to dismiss 11 *qui tam* complaints pending in district courts across the country.[1] The complaints alleged that defendant pharmaceutical manufacturers and third-party vendors provided illegal kickbacks in the form of free nursing services and free reimbursement support to health care providers and patients. Each complaint was brought by a corporate subsidiary of National Health Care Analysis Group (NHCA Group), a limited liability company formed by investors and former Wall Street investment bankers solely to serve as a *qui tam* relator. The government's motions to dismiss these complaints harshly criticized the relators' business model, recognized the significant cost to the government of investigating and litigating these claims, and acknowledged that manufacturers' provision

of educational information and instruction to patients can be appropriate and beneficial to federal health care programs and their beneficiaries.[2] The recent motions are instructive to drug and device manufacturers defending *qui tam* litigation and implementing patient education and other product support programs.

The Government's Motions

NHCA Group is a limited liability company that formed various companies solely for the purpose of serving as relators in *qui tam* lawsuits against pharmaceutical companies. Each of the NHCA Group's complaints alleged that programs that help patients obtain insurance coverage for their treatment or provide nursing assistance to patients constituted illegal kickbacks.

The government's motions to dismiss focused on NHCA Group's status as a made-for-litigation relator. The government denounced NHCA's opportunistic and deceptive information-gathering model for its *qui tam* suits — which solicited "potential informants" to engage in paid interviews under the false pretense of unbiased industry research, and harnessed "vast amounts of Medicare claims data available to the public" as a "massive business opportunity" for *qui tam* litigation. It also emphasized the near-verbatim recitation of factual allegations and theories of liability throughout the NHCA Group's multiple complaints, highlighting its wide-reaching claims that, in the aggregate, implicated 73 million prescriptions reimbursed by Medicare Part D.

With this backdrop, the government argued that dismissal of the complaints would advance the governmental interests of preserving limited resources and protecting the policy priorities of federal health care programs. As to its scarce resources, the government noted that it expended substantial resources investigating NHCA Group's expansive allegations across these *qui tam* complaints and found generally that the claims "lacked adequate support." Given the "vast" geographic and temporal scope of the allegations, the government identified concerns around the investigative and litigation burdens that these allegations would pose for the United States.

Most significant for the health care industry is the government's acknowledgement that providing educational information and instruction to patients is consistent with the goals of federal health care programs. Recognizing that the relators' allegations "conflict with important policy and enforcement prerogatives of the federal government's healthcare programs," the government went on to say:

> For instance, relators allege that the provision of educational information and instruction to patients constitutes illegal kickbacks to physicians. But given the vast sums the government spends on the medications at issue, federal healthcare programs have a strong interest in ensuring that, after a physician has appropriately prescribed a medication, patients have 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. In another context, HHS-OIG has advised that the provision of educational materials or informational programs to patients, without more, does not constitute remuneration. These relators should not be permitted to indiscriminately advance claims on behalf of the federal 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.[3]

These assertions are not binding guidance, but they provide an instructive and much-needed framework for industry.

Key Takeaways

While DOJ currently is focused on thwarting the efforts of this novel for-profit relator-entity and it is likely that it will continue to exercise significant discretion in seeking dismissal of *qui tam* claims, defendants/manufacturers should draw several important and widely applicable lessons from these recent motions.

First, defendant manufacturers should focus on the identity of the *qui tam* relator and the methods by which the relator obtained the evidence supporting the complaint, and, if appropriate, should consider related discovery. The government's reasoning in these recent motions may extend to challenges of other *qui tam* relators that have no firsthand knowledge of the alleged fraud, such as relators that are not "industry insiders" or that obtain the information underlying their *qui tam* complaints using unscrupulous or deceptive means.

Second, even after the government has declined to intervene in a *qui tam* case, defendants should remain engaged with the government and affirmatively bring its attention to the likelihood of investigative and litigation burdens that may impact not only DOJ, but FDA, CMS, or other relevant agencies. At all stages of litigation, defendants should advocate that the government weigh the burden imposed on these agencies against the merits of the relators' claims in considering whether dismissal is warranted.

Third, DOJ clearly supports the "common industry practice" of providing educational information and instruction to patients and acknowledges that these practices are consistent with the interests of federal health care programs, particularly when they provide support to patients with serious conditions requiring costly medications. The government also has reiterated OIG Guidance that "the provision of educational materials or information programs to patients, without more, does not constitute 'remuneration.'"[4] Patient education and reimbursement support programs must be evaluated individually and cannot provide substantial independent value to physicians or patients or interfere with clinical decision making. The government, however, has now acknowledged that ***after*** a physician has ***appropriately prescribed*** a medication, it is ***appropriate and beneficial*** to provide ***basic product support***, which can include a patient-assistance phone line, injection training and educational support. Drug and device manufacturers should pay close attention to this broad framework as they design, implement and monitor these necessary patient support programs.

Endnotes

1 31 U.S.C. § 3730(c)(2)(A) states: "The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion." Notably, in January 2018, DOJ issued an internal memorandum (commonly referred to as the Granston Memo) that addressed this dismissal provision and, noting the significant increase in *qui tam* actions, outlined seven, nonexhaustive factors to be considered as a basis for dismissal. These factors included curbing meritless *qui tam* suits, preventing opportunistic or parasitic relators, and preventing interference with agency policies and programs — all reasons that the government cited as supportive of the motions to dismiss discussed herein.

2 *See, e.g.,* Memorandum of Law in Support of the United States' Motion to Dismiss Relator's First Amended Complaint, *United States ex rel. NHCA-Tev, LLC v. Teva Pharm. Prods. Ltd.,* No. 17-2040 (E.D. Pa. Dec. 17, 2018), http://www.pepperlaw.com/resource/33798/20I2. The authors are counsel to Teva Pharmaceutical Products Ltd. in this matter pending in the Eastern District of Pennsylvania.

3 *Id.* (internal citation omitted).

4 *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,735 (2003).

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