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February 6, 2018

DOJ POLICY STATEMENTS SIGNAL CHANGES IN FALSE CLAIMS ACT ENFORCEMENT

To Our Clients and Friends:

The Department of Justice issued two internal memoranda in January that, taken together, reflect the Trump Administration's first significant policy statements on False Claims Act (FCA) enforcement. The first memorandum directs government attorneys evaluating a recommendation to decline intervention in a *qui tam* FCA suit to consider in addition whether to exercise DOJ's authority to seek dismissal of the case outright. The second prohibits DOJ from relying on a defendant's failure to comply with other agencies' guidance documents as a basis for proving violations of applicable law in affirmative civil enforcement actions. The practical effects of these statements on FCA enforcement will only be clear when we see how – and how often – they are applied in actual cases. But particularly when coupled with the Supreme Court's landmark decision on scienter and materiality in *Universal Health Services v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), these DOJ memoranda provide substantial arguments for FCA defendants in seeking to defeat FCA claims.

Exercise of DOJ's Dismissal Authority

On January 10, 2018, Michael Granston, the Director of the Fraud Section of DOJ's Civil Division, issued a memorandum directing government lawyers evaluating a recommendation to decline intervention in a *qui tam* FCA action to "consider whether the government's interests are served . . . by seeking dismissal pursuant to 31 U.S.C. § 3730(c)(2)(A)." DOJ did not publicly release the memorandum at the time, but it has now been widely reported and is available here.

DOJ has authority under section 3730(c)(2)(A) to seek dismissal of *qui tam* FCA suits. Traditionally, the government has exercised this authority only sparingly. But, as we discussed in our year-end FCA update (found here), Mr. Granston hinted previously at a change in policy with respect to dismissal of meritless *qui tam* suits. Despite DOJ's denial at the time that any policy changes had been implemented, the memorandum appears to confirm a policy shift in favor of more actively seeking dismissal of certain *qui tam* FCA actions.

The memorandum notes that DOJ "has seen record increases in *qui tam* actions" filed under the FCA, and while the "number of filings has increased substantially over time," DOJ's "rate of intervention has remained relatively static." Emphasizing that DOJ "plays an important gatekeeper role in protecting the False Claims Act," the memorandum identifies dismissal as "an important tool to advance the government's interests, preserve limited resources, and avoid adverse precedent."

Under the memorandum, DOJ attorneys should consider dismissal:

1. Where "a *qui tam* complaint is facially lacking in merit," or where, after completing an investigation, the government concludes that the relator's allegations lack merit.

2. Where a *qui tam* action "duplicates a pre-existing government investigation and adds no useful information to the investigation."

3. Where "an agency has determined that a *qui tam* action threatens to interfere with an agency's policies or the administration of its programs and has recommended dismissal to avoid these effects."

4. Where "necessary to protect the Department's litigation prerogatives," such as "to avoid interference with pending Federal Torts Claim Act action" or "to avoid the risk of unfavorable precedent."

5. When necessary "to safeguard classified information," particularly in cases "involving intelligence agencies or military procurement contracts."

6. To preserve government resources "when the government's expected costs are likely to exceed any expected gain," (e.g., in situations where the government will incur the costs of "monitor[ing] or participat[ing] in ongoing litigation, including responding to discovery requests").

7. Where there are "problems with the relator's action that frustrate the government's efforts to conduct a proper investigation."

The memorandum cites cases illustrating each factor. This list, the memorandum observes, is not exhaustive, and the seven factors are not mutually exclusive. Further, "there may be other reasons for concluding that the government's interests are best served by the dismissal of a *qui tam* action." The memorandum also notes that "there may be alternative grounds for seeking dismissal," such as under "the first to file bar, the public disclosure bar, the tax bar, the bar on *pro se* relators, or Federal Rule of Civil Procedure 9(b)."

The federal courts have split on the extent of DOJ's authority to dismiss *qui tam* actions under section 3730(c)(2)(A). While DOJ takes the position that it has "unfettered" discretion to dismiss *qui tam* FCA suits, the memorandum advises attorneys to argue in jurisdictions that adopt a "rational basis" standard that the standard was intended to be "highly deferential." In jurisdictions where the standard of review is not settled, the memorandum instructs DOJ attorneys "to identify the government's basis for dismissal and to argue that it satisfies any potential standard for dismissal under section 3730(c)(2)(A)."

Reliance on Agency Guidance in Affirmative Civil Enforcement Cases

Associate Attorney General Rachel Brand, the Department's third-ranking official, issued a memorandum on January 25, 2018, that prohibits DOJ from using noncompliance with other agencies'

"guidance documents as a basis for proving violations of applicable law in" affirmative civil enforcement cases (ACE cases), and from using "its enforcement authority to effectively convert agency guidance documents into binding rules." The memorandum is available here.

Agencies commonly issue guidance documents interpreting legislation and regulations, and the government has sometimes employed evidence that a defendant violated such guidance to prove a violation of the underlying statute or regulation. The memorandum explicitly prohibits DOJ attorneys from engaging in this practice. Under the new policy, DOJ "may continue to use agency guidance documents for proper purposes." For instance, where a guidance document "simply explain[s] or paraphrase[s] legal mandates from existing statutes or regulations," DOJ "may use evidence that a party read such a guidance document to help prove that the party had requisite knowledge of the mandate." Notably, the memorandum applies to both "future ACE actions brought by the Department, as well as (wherever practicable) to those matters pending as of the date of this memorandum."

The Brand memorandum carries forward to ACE actions a policy established by Attorney General Jeff Sessions in a November 16, 2017, memorandum. In that memorandum, Attorney General Sessions prohibited Department components from issuing guidance documents that purport to create rights or obligations binding on persons "without undergoing the rulemaking process," and from "using its guidance documents to coerce regulated parties into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or lawful regulation." The Brand memorandum provides that the principles articulated by Attorney General Sessions "should guide Department litigators in determining the legal relevance of other agencies' guidance documents."

While the policy articulated in the Brand memorandum applies to more than just FCA suits, the memorandum specifically emphasizes that it "applies when the Department is enforcing the False Claims Act, alleging that a party knowingly submitted a false claim for payment by falsely certifying compliance with material statutory or regulatory requirements." That the memorandum uses FCA enforcement suits as its only illustrative example could suggest that the Department is particularly focused on the policy's application to FCA cases.

Analysis

The Granston and Brand memoranda reflect the most significant policy statements on FCA enforcement from DOJ under Attorney General Sessions. As our year-end update explained, FCA enforcement remained robust in the first year of the Trump Administration, and on several occasions the new DOJ leadership expressed public support for continued strong enforcement of the law. The policy statements signal a shift in approach, at least in some cases. The full effect of these policy statements will be determined over time as they are applied in actual cases, but a few observations are warranted now.

- ***First, although the Granston memorandum may have some salutary effects for FCA defendants (as noted below), the Brand memorandum is likely to be the more significant development, especially in the wake of* Escobar.** Recently, courts have relied on *Escobar* to set

aside judgments on the ground that alleged misrepresentations were not material to the government's payment decision.

In a 2017 decision, for example, the Fifth Circuit overturned a $663 million judgment—the largest judgment in FCA history—on the ground that a purported misrepresentation was not material because the government knew of the misrepresentation and yet continued to pay. *United States ex rel. Harman v. Trinity Industries*, 872 F.3d 645, 663 (5th Cir. 2017). In assessing materiality, the Fifth Circuit also relied on the fact that DOJ declined to intervene in the suit. Likewise, in January 2018, a district court vacated a $350 million jury verdict after concluding that the relator failed to offer any evidence that the misrepresentation was material. There, again, the government was aware of the alleged regulatory noncompliance underlying the suit but nevertheless continued to pay the defendants' claims. The court recognized this as "strong" and uncontroverted evidence that noncompliance with the requirement was immaterial. *United States ex rel. Ruckh v. GMC II LLC et al.*, 2018 WL 375720, at *10 (M.D. Fla. Jan. 11, 2008).

The Brand memorandum, coupled with courts taking *Escobar*'s materiality discussion seriously, has the potential to be a strong pro-defendant development. Historically, agency guidance documents appeared frequently in FCA cases. Before the Brand memorandum, it looked likely that, as the government contended with heightened materiality requirements under *Escobar*, it would routinely invoke such guidance documents to establish the importance of a misrepresentation to a payment decision. Now, where a defendant can show that the guidance document does more than merely restate the underlying law, DOJ will not be able to make such arguments.

This may have important ramifications for FCA defendants from several industries. For example, a significant number of Medicare-based FCA cases could be affected if the Medicare Benefit Policy Manual is considered an "agency guidance document." Moreover, many anti-kickback cases rely on guidance documents issued by the Office of Inspector General (OIG) of the Department of Health and Human Services. By eliminating agency guidance documents as a means to establish liability, the Brand memorandum could significantly reduce the range and scope of conduct that can give rise to FCA liability.

The Brand memorandum also dovetails with the Granston memorandum. Suppose that a relator asserts a claim under the FCA that is based on a theory that a defendant falsely certified compliance with a requirement, but that requirement is found only in an agency guidance document. FCA defendants can rely on materiality arguments at the motion to dismiss or summary judgment stages, but could also rely on the Granston memorandum to advocate that DOJ recommend dismissal at the point of declination, on the grounds that dismissal is "necessary to protect the Department's litigation prerogatives" (namely, DOJ's policy of not using noncompliance with other agencies' guidance documents as a basis for proving violations of applicable law).

Finally, the Brand memorandum is part of a broader trend that has reduced the ways in which a claim can be "false." A growing number of courts have declined to find false claims where there is no evidence of an "objective falsehood," such as in cases where a claim is premised on battling expert interpretations of an ambiguous statute or regulation, or where based on competing medical opinions. The Brand memorandum will make it harder than ever for DOJ to prove, for example, that a claim was "false" because it sought payment for services that were not "medically necessary." First, in line with recent court decisions, DOJ cannot, in attempting to prove falsity, rely solely on its own expert's disagreement with the treating provider about what was "necessary." Second, under the Brand memorandum, DOJ cannot rely on agency guidance documents construing what is "medically necessary" to prove liability. While this prohibition could eliminate the Medical Benefit Policy Manual as a source for proving falsity, it will also presumably rule out national and local coverage determinations issued by program contractors, determinations that DOJ attorneys previously claimed were binding.

- ***Second, nothing in the Brand memorandum suggests that the government will be able to use this policy decision to limit a defendant's use of guidance documents to defend itself.*** To the contrary, the courts have been clear that all evidence that impacts a defendant's state of mind, including government statements, is admissible on the FCA's scienter element. *See, e.g.*, *United States ex rel. Walker v. R&F Props. Of Lake Cnty, Inc.*, 433 F.3d 1349, 1356–58 (11th Cir. 2005) (deeming Medicare manuals and expert testimony relevant to show "the reasonableness of [defendant's] claimed understanding of that language," and rejecting the district court's holding that such evidence was "irrelevant . . . because none of it held the force of law.").

  And although it has been reported that DOJ criminal attorneys have emphasized that they are not bound by the Brand memorandum, the underlying legal principle applies equally to criminal cases: the executive branch should not, through agency documents, define the substantive scope of penal laws. *Cf., e.g.*, *Carter v. Welles-Bowen Realty, Inc.*, 736 F.3d 722, 730 (6th Cir. 2013) (Sutton, J., concurring) ("[T]he rule of lenity forbids deference to the executive branch's interpretation of a crime-creating law.").

- ***Third, DOJ's commitment to exercise its authority to dismiss* qui tam *actions is welcome news to FCA defendants given that relators have pursued cases more frequently even when DOJ has declined to intervene.*** Historically, declined cases rarely led to significant recoveries, a sign of the relative weakness of such cases overall. In 2017, the government recovered nearly $426 million in cases where it declined to intervene, the second-highest amount on record. Although that amount accounted for just 11% of all federal recoveries in 2017, the promise of significant recoveries in declined cases might tempt relators to pursue weak cases. To the extent that DOJ attorneys employ the Granston memorandum's factors to terminate such cases before defendants incur further litigation costs, defendants may enjoy some relief from the active relators' bar.

  On the other hand, the memorandum also observes that declination decisions frequently cause relators to dismiss their claims, and that that the number of voluntarily dismissed actions "has significantly reduced the number of cases where the government might otherwise have

considered seeking dismissal pursuant to section 3730(c)(2)(A)." This point could reflect DOJ's view that the pool of cases in which dismissal is appropriate is small. Further, the Granston memorandum does not apply to FCA retaliation claims, or to claims brought under state FCA statutes. The memorandum could encourage *qui tam* plaintiffs to assert these sorts of claims in order to prevent their suits from being dismissed outright. These dynamics may limit the practical benefits of the memorandum for some FCA defendants.

- ***Fourth, the Granston memorandum equips* qui tam *defendants with an arsenal of relevant arguments supporting dismissal.*** In the past, FCA defendants have been forced to guess what arguments DOJ might find persuasive in deciding whether to invoke its authority under section 3730(c)(2)(A). By specifying key factors and articulating the overall standard, the memorandum provides FCA defendants an analytical structure for advocating to DOJ that a relator's case is meritless and should be dismissed before litigation (i.e., before incurring the expenses associated with motion to dismiss briefing, discovery, and summary judgment briefing). The Granston memorandum also cites cases illustrating each dismissal factor. *Qui tam* defendants should consider whether their case is factually similar to these illustrative cases. DOJ will likely hesitate to move for dismissal of a *qui tam* suit unless they are confident the motion will be granted. FCA defendants who are able to show that precedent supports dismissal of their case have an increased likelihood of persuading DOJ to seek dismissal.

  Relatedly, the memorandum also will spur increased internal scrutiny within DOJ of dismissal questions. The assigned DOJ case team will internally review whether dismissal is appropriate at every declination decision, and the case team's dismissal decision will be reviewed by component supervisors and tracked as a statistic by DOJ. In other circumstances, just by tracking statistics on a policy shift of this nature, DOJ has nudged its attorneys toward the intended result. Here, internal attention and tracking should increase the likelihood that DOJ attorneys recommend dismissing *qui tam* FCA suits.

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In sum, there is reason to be optimistic that these two DOJ memoranda will have the effect of scaling back FCA enforcement. Moreover, because the Brand memorandum applies to cases currently pending as of its issuance "wherever practicable," companies currently facing FCA liability should carefully consider whether the enforcement theory is rooted in the underlying statute or regulation, or is only supported by a guidance document.

The following Gibson Dunn lawyers assisted in preparing this client update: Stuart Delery, Winston Chan, John Partridge, Stephen Payne, Jonathan Phillips, Charles Stevens and Justin Epner.

Gibson Dunn's lawyers have handled hundreds of FCA investigations and have a long track record of litigation success. Among other significant victories, Gibson Dunn successfully argued the landmark Allison Engine case in the Supreme Court, a unanimous decision that prompted Congressional

action. See Allison Engine Co. v. United States ex rel. Sanders, 128 S. Ct. 2123 (2008). Our win rate and immersion in FCA issues gives us the ability to frame strategies to quickly dispose of FCA cases. The firm has more than 30 attorneys with substantive FCA expertise and more than 30 former Assistant U.S. Attorneys and DOJ attorneys.

As always, Gibson Dunn's lawyers are available to assist in addressing any questions you may have about these developments. To learn more about these issues, please contact the Gibson Dunn lawyer with whom you usually work, the authors, or any of the following.

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