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PRATT'S GOVERNMENT CONTRACTING LAW REPORT

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Editor's Note: GAO Protest Reform
Victoria Prussen Spears 147

Pursuing Self-Interest While Achieving Oversight: GAO Protest Reform Should Look To Process, Not Politics—Part I
Stuart W. Turner, Charles A. Blanchard, Sonia Tabriz, and Nathan Castellano 149

False Claims Act Circuit Splits—FCA Issues That May Soon Reach the Supreme Court or Lead to Congressional Amendment—Part II
Robert S. Salcido 156

False Claims Act: 2017 Year-in-Review—Part I
Jonathan G. Cedarbaum and Christopher E. Babbitt 166

Is DOJ Changing Its Approach to Enforcement? What Regulated Entities Need to Know
D. Jacques Smith, Randall A. Brater, and Michael F. Dearington 178

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Is DOJ Changing Its Approach to Enforcement? What Regulated Entities Need to Know

By D. Jacques Smith, Randall A. Brater, and Michael F. Dearington*

The trio of recent Department of Justice memoranda that shed light on the Department's enforcement policies have generated significant interest among businesses operating in highly regulated industries, such as health-care and government contracting. The authors of this article describe the specific policy, purpose, and potential impact of each memo.

Three Department of Justice ("DOJ") memoranda recently emerged that shed light on DOJ enforcement policies—two published memos that restrict DOJ's use of agency guidance, and one leaked memo that directs DOJ attorneys to consider moving to dismiss meritless *qui tam* (i.e., whistleblower) complaints brought under the federal False Claims Act ("FCA").

The trio of DOJ memos have generated significant interest among businesses operating in highly regulated industries, such as healthcare and government contracting. This article describes the specific policy, purpose, and potential impact of each memo. In sum, while the guidance-related memos are consistent with the Trump Administration's overall regulatory-reform agenda, they are unlikely to translate to a reduced number of enforcement actions under the False Claims Act, the Anti-kickback Statute, and other statutes that are strictly enforced by DOJ. Moreover, although the memos may cause DOJ to take less-aggressive litigation positions buttressed only by agency guidance, courts remain free to rely on such guidance as persuasive authority.

With respect to the memo regarding *qui tam* dismissals, regulated entities faced with meritless FCA actions may have additional arguments as to why DOJ should seek dismissal, rather than merely decline to intervene in a case, which could lead to an uptick in the number of voluntary dismissals by relators

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or DOJ. On the whole, although the trio of memos are helpful to regulated entities, they do not signal a "free pass" to ignore or limit their focus on compliance or helpful agency guidance. Ensuring compliance with statutes and regulations, and promptly addressing FCA concerns with experienced counsel, remain paramount to avoiding significant liability under the FCA.

THE GUIDANCE POLICY: "IMPROPER GUIDANCE DOCUMENTS"

Policy Summary

On November 16, 2017, Attorney General Jeff Sessions publicly issued a memo to DOJ that prohibits issuance of DOJ "guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch." The Guidance Policy requires that DOJ guidance documents clearly indicate that they are non-binding guidance, and forbids DOJ from using these documents to "coerce" persons to take or avoid taking action beyond what is required by statutes or regulations. The policy applies to "any Department statements of general applicability and future effect, whether styled as guidance or otherwise," designed to advise persons about legal rights and obligations, but does not apply to adjudicatory actions that bind only the parties involved, or internal DOJ policies or directives. The memo also directs Associate Attorney General Rachel Brand and the Regulatory Reform Task Force to identify existing DOJ guidance documents that should be repealed, replaced, or modified based on the new policy.

Purpose

Consistent with the Trump Administration's regulatory-reform agenda and Executive Order No. 13777, the policy is aimed at ensuring that DOJ adheres to the principle "that agencies regulate only within the authority delegated to them by Congress," and also adhere to the Administrative Procedure Act's notice-and-comment rulemaking procedure when establishing binding rights or obligations.

Potential Impact

- DOJ, through its Regulatory Reform Task Force, has already withdrawn 25 of its policy-guidance documents, on a diverse range of subjects from explosives permits to the Americans with Disabilities Act.[1]
- Notably, the Guidance Policy does not apply to key DOJ internal

[1] For the full list, which the Task Force may look to expand, see https://www.justice.gov/opa/pr/attorney-general-jeff-sessions-rescinds-25-guidance-documents.

policy documents, such as the memo addressing "Individual Accountability for Corporate Wrongdoing" (September 9, 2015) (the "Yates Memo"), or the memo on "Departmental Charging and Sentencing Policy" (May 10, 2017), which requires that prosecutors charge defendants with provable offenses that carry the highest possible sentences.

- The future significance of the Guidance Policy will depend, in part, on how DOJ implements the policy, and which DOJ guidance is withdrawn. Its greatest impact could arise from its effect on other agencies, as the memo states that DOJ should be the "model" for "lawful exercise of regulatory power." Only time will tell whether other agencies will follow suit by issuing similar memos and withdrawing substantive guidance documents.

THE BRAND MEMO: "LIMITING USE OF AGENCY GUIDANCE DOCUMENTS IN AFFIRMATIVE CIVIL ENFORCEMENT CASES"

Policy Summary

On January 25, 2018, Associate Attorney General Rachel Brand issued a public memo restricting DOJ attorneys' reliance on guidance from other federal agencies in civil-enforcement matters. The Brand Memo aims to avoid the practice of "convert[ing] agency guidance documents into binding rules," and therefore prohibits use of an agency guidance document to presumptively or conclusively establish that a person violated a statute or regulation in civil-enforcement matters, because "agency guidance documents cannot create any additional legal obligations."

Purpose

Consistent with the Guidance Policy discussed above, appropriate delegation of congressional authority, and the Administrative Procedure Act, the Brand Memo is aimed at ensuring that DOJ attorneys in civil-enforcement cases do not treat guidance documents, which have not undergone notice-and-comment rulemaking, as though they create binding legal obligations on persons or entities.

Potential Impact

- The Brand Memo could have a significant impact on cases brought under the False Claims Act, DOJ's primary anti-fraud tool. In bringing FCA suits, DOJ often cites and relies on agency guidance that represent the most stringent interpretations of statutes and regulations. These can include guidance such as the Office of Inspector General for the U.S. Department of Health and Human Services' "special fraud alerts" and

"special advisory bulletins" that discuss the Anti-Kickback Statute ("AKS"), Centers for Medicare & Medicaid Services manuals regarding Medicare and Medicaid billing and coding, and Food and Drug Administration's industry guidance regarding labeling. This allows DOJ to take aggressive litigation positions, bolstered by agency positions that have not undergone notice-and-comment rulemaking. Absent the ability of DOJ attorneys to rely on agency guidance, DOJ's appetite to take overly aggressive litigation positions in FCA suits may decrease. That said, the policy could result in the ironic circumstance where a *qui tam* relator who brings an FCA suit may rely on agency guidance to take an aggressive litigation position, but the DOJ attorneys who intervene and take over the case will not do so.

- The Brand Memo expressly excepts DOJ's use of agency guidance in civil-enforcement actions to (1) paraphrase or explain statutes and regulations, or (2) prove that the defendant had knowledge of the particular statute or regulation. DOJ will likely continue to use agency guidance in this way going forward.
- Courts, unlike DOJ attorneys, can continue to refer to agency guidance as persuasive authority when interpreting ambiguous statutes and regulations in civil-enforcement actions. The bigger question, then, may be whether courts will continue to rely on agency guidance when interpreting statutes and regulations, even if DOJ does not explicitly do so.

THE GRANSTON MEMO: "FACTORS FOR EVALUATING DISMISSAL PURSUANT TO 31 U.S.C. § 3730(C)(2)(A)" OF THE FALSE CLAIMS ACT

Policy Summary

On January 10, 2018, Michael Granston, Director of DOJ's Civil Fraud Section, issued an internal "privileged and confidential" memo that outlines seven factors that inform when it may be appropriate for DOJ to move for voluntary dismissal of a meritless *qui tam* FCA suit brought by a relator. The Granston Memo notes that, when DOJ attorneys decline intervention, they "should also consider whether the government's interests are served . . . by seeking dismissal," in whole or in part, under 18 U.S.C. § 3730(c)(2)(A), which allows DOJ to move for dismissal of *qui tam* complaints. The seven factors DOJ attorneys should consider are:

(1) curbing meritless *qui tams*;

(2) preventing parasitic or opportunistic *qui tam* actions;

(3) preventing interference with agency policies and programs;

(4) controlling litigation brought on behalf of the United States;

(5) safeguarding classified information and national-security interests;

(6) preserving government resources; and

(7) addressing egregious procedural errors by the relator.

Purpose

Consistent with Director Granston's comments at a conference back in October, the Granston Memo aims to reduce the costs to the government of monitoring and sometimes providing discovery in meritless *qui tam* cases, and also aims to avoid situations where relators create bad FCA case law that affects future DOJ enforcement matters.

Potential Impact

- *Qui tam* suits are here to stay. They continue to be DOJ's greatest source of recoveries; according to DOJ statistics, 674 of the 799 new FCA matters in FY 2017 originated from whistleblower referrals and *qui tam* suits. These matters led to roughly $3.4 billion of the $3.7 billion in total FCA recoveries in FY 2017, or nearly 93 percent, while non-*qui tam* matters amounted to only about $266 million of all FCA recoveries. The resulting investigations are unlikely to decrease, either, as DOJ has a statutory obligation to investigate potential FCA violations, under 31 U.S.C. § 3730.
- The Granston Memo is nevertheless beneficial to entities that directly or indirectly benefit from government expenditures, as early dismissal by DOJ allows a defendant to avoid the costs of litigating and moving to dismiss under Rule 9(b) (failure to plead fraud with particularity), Rule 12(b)(6) (failure to state a claim upon which relief can be granted), or on other grounds. Defendants should therefore look for opportunities to advocate for dismissal of meritless *qui tam* complaints based on the Granston factors when meeting with DOJ. Especially in districts with significant FCA-enforcement activity, DOJ will likely be interested in avoiding situations where an inexperienced relator's counsel might fail to effectively represent DOJ's views, leading to bad case law. In light of a recent reluctance by some courts to allow DOJ to be heard after declining intervention, through filing a "Statement of Interest," this argument may be particularly persuasive.
- Rather than leading to a significant uptick in voluntary dismissals by DOJ, the Granston Memo may instead lead to an increase in voluntary dismissals by relators. Typically, when DOJ attorneys believe a *qui tam* suit is meritless, they inform the relator's counsel of the weaknesses in

the case and can effectively convince the relator's counsel to move for dismissal. In light of the Granston Memo, DOJ attorneys may be more likely to advocate for dismissal by the relator by threatening dismissal by DOJ. The best way to gauge the effectiveness of the Granston Memo may therefore be to examine the rate of voluntary dismissals by either the relator or the government in the years to come.

Although it is critical for a company to be familiar with DOJ policies when confronting a DOJ enforcement action, it can be even more important for companies in highly regulated industries to take proactive measures to avoid such actions. Companies should therefore continue to devote appropriate resources to strong compliance programs, and address potential FCA concerns before they snowball into substantial exposure under the FCA.