

DOJ Memorandum Addressing Agency Guidance

March 8, 2018

On January 25, the Department of Justice (the “DOJ”) released a memorandum by former Associate Attorney General Rachel Brand (the “Brand Memo”) prohibiting the DOJ from relying on noncompliance with other agencies’ guidance documents as evidence of a defendant’s violation of applicable law. While the Brand Memo is arguably only a restatement of the established principle that agency guidance is nonbinding, it may nevertheless have important implications for cases brought by the DOJ under the False Claims Act (the “FCA”) and other enforcement actions.



BRAND MEMO OVERVIEW

The Brand Memo prohibits the DOJ from using “its enforcement authority to effectively convert agency guidance documents into binding rules” by using a party’s noncompliance with other agencies’ “guidance documents as a basis for proving violations of applicable law” in affirmative civil enforcement (“ACE”) cases. It also 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 Memo follows a directive from Attorney General Sessions, dated November 16, 2017, prohibiting all DOJ sections from issuing “guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch.”¹ This directive required the DOJ to refrain from using its own guidance documents to “coerc[e]” persons to take or avoid taking actions beyond what is required by statutes or regulations. These memos highlight the DOJ’s increased skepticism of “rulemaking by guidance.”

It should be noted that the Brand Memo permits the DOJ to rely upon agency guidance to paraphrase or explain statutes and regulations, and to prove that a party had knowledge of a particular statute or regulation. It does not elaborate on these scenarios.

¹ “Memorandum for All Components: Prohibition of Improper Guidance Documents,” from Attorney General Jefferson B. Sessions III, November 16, 2017, available at <https://www.justice.gov/opa/press-release/file/1012271/download>.

The breadth of the carve-outs poses a risk that the exceptions will swallow the rule. However, in light of the Trump administration's disapproval of the use of guidance documents, it is unlikely that these exceptions will be widely invoked.

IMPLICATIONS OF THE BRAND MEMO

Implications for FCA Actions Brought by the DOJ

The Brand Memo is likely to reduce, if not eliminate, the circumstances in which the DOJ brings FCA actions predicated on failures to comply with agency guidance documents. Instead, the DOJ will be confined to proving violations based on the text of the applicable statutes or regulations. This development will be particularly relevant in certain industries:

- In the **life sciences** sector, where DOJ attorneys often rely on guidance issued by the Department of Health and Human Services' Office of the Inspector General and Food and Drug Administration.
- In the **healthcare sector**, where DOJ attorneys often rely on the Centers for Medicare & Medicaid Services' Medicare Benefit Policy Manual.
- In the **mortgage sector**, where DOJ attorneys often rely on provisions of the HUD Handbook or on Mortgagee Letters issued by the Department of Housing and Urban Development.

In light of the Brand Memo, the DOJ may no longer be able to argue that defendants' reimbursement submissions were false because the defendants were not in compliance with the applicable standards set forth in agency guidance.

Many FCA cases also turn on whether or not any alleged false statements were material. In *Universal Health Services v. United States ex rel. Escobar*,² the Supreme Court held that FCA plaintiffs must satisfy a "rigorous" materiality standard, i.e., that the government would not have provided reimbursement had it known about the alleged false statement. In light of the Brand Memo, the DOJ may no longer be able to rely on agency guidance to establish the importance to an agency decision of a defendant's misrepresentation. It therefore may be more difficult in some circumstances for the DOJ to satisfy *Escobar's* heightened materiality requirement.

² 136 S. Ct. 1989 (2016).

A few examples highlight the circumstances in which the DOJ relied on agency guidance in the past but might not be able to do so in the future in light of the Brand Memo:

- In 2012, the DOJ brought an FCA action against Life Care Centers of America, a large skilled nursing home operator. The DOJ alleged that the defendant engaged in a scheme to increase revenue by placing as many patients as possible in the highest reimbursement category for skilled rehabilitation therapy even though such therapy was often not medically reasonable and necessary. The complaint relied on the Medicare Benefit Policy Manual, which is an agency guidance document, to explain what types of skilled rehabilitation therapy are appropriate. This matter ultimately settled in 2016 for \$145 million.³
- Last year, the DOJ announced the settlement of an FCA action against Residential Home Funding Corporation, an entity that originates residential mortgages. The DOJ alleged that the defendant made false statements in order to participate in a government program under which it had the authority to endorse mortgages for Federal Housing Administration insurance (meaning that the federal government would cover losses on loans that defaulted). The DOJ's allegations were premised in part on the defendant's failure to follow requirements set forth in the Department of Housing and Urban Development Handbooks, which are agency guidance documents. This matter was settled for \$1.67 million.⁴

The Brand Memo also casts doubt on the DOJ's ability to rely on the Auer deference, a well-known but often-challenged doctrine providing that courts should defer to an agency's interpretation of its own regulations, as set forth in that agency's own guidance documents, unless the agency's interpretation is clearly erroneous.⁵

Implications for FCA Actions Brought by Relators

FCA actions can be brought by relators, private individuals who allege misconduct related to false claims for government reimbursement or other government benefits. If the DOJ declines to intervene in an action brought by a relator, the relator can elect to proceed alone. While the Brand Memo technically applies only to actions led by the DOJ, it has potentially significant implications for actions prosecuted by relators as well.

³ "Life Care Centers of America, Inc. Agrees to Pay \$145 Million to Resolve False Claims Act Allegations Relating to the Provision of Medically Unnecessary Rehabilitation Care," October 24, 2016, available at <https://www.justice.gov/usao-edtn/pr/life-care-centers-america-inc-agrees-pay-145-million-resolve-false-claims-act>.

⁴ "Acting Manhattan U.S. Attorney Settles Civil Mortgage Fraud Lawsuit Against Residential Home Funding Corp.," September 28, 2017, available at <https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-settles-civil-mortgage-fraud-lawsuit-against-residential>.

⁵ *Auer v. Robbins*, 519 U.S. 452, 461 (1997).

The Brand Memo was issued shortly after a leaked internal memorandum by Michael Granston, the Director of the DOJ Civil Division's Fraud Section, which outlined the circumstances in which DOJ attorneys should seek early dismissal of FCA actions (the "Granston Memo").⁶ The Granston Memo described the substantial increase in actions led by relators alone and argued that the DOJ should consider invoking its statutory authority to seek early dismissal of such cases when they impose significant burdens on the DOJ. For example, each of these cases still must be actively monitored by the DOJ, and the rulings issued in such cases may create precedents that negatively impact the DOJ's ability to litigate its own FCA cases. To the extent that a case brought by a relator acting alone relies on agency guidance, FCA defendants can now use the Brand Memo to argue to the DOJ that the case should be dismissed because the reliance on guidance documents is improper. Even if the DOJ does not elect to try and dismiss a case, the Brand Memo gives FCA defendants ammunition to argue that relators who stand in the shoes of the DOJ should not be permitted to rely on agency guidance.

Implications for Use by Defendants to Establish Compliance

The Brand Memo does not preclude defendants from using agency guidance documents to establish that they complied with applicable standards set forth in agency documents. At the very least, proof of compliance with standards described in agency guidance should negate allegations that the defendant was acting with knowledge of wrongdoing.⁷

Implications for Criminal Cases and Administrative Enforcement Actions

Even though the Brand Memo applies only to ACE actions brought by the DOJ Civil Division, its logic extends to other contexts as well. The underlying principle that "guidance documents cannot create binding requirements that do not already exist by statute or regulation" should apply equally to actions brought by the DOJ Criminal Division and to enforcement actions brought by other agencies. Whether that happens remains to be seen.

⁶ "Factors for Evaluating the Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)," from Director of Commercial Litigation Branch, Fraud Section Michael D. Granston, January 10, 2018, available at https://drive.google.com/file/d/1PjNaQyopCs_KDWy8RL0QPAEIPtnv31ph/view. For additional information, please consult our recent client update, titled "DOJ Creates Potential Openings for Early Dismissal of False Claims Act Suits," available at <https://www.debevoise.com/insights/publications/2018/01/doj-creates-potential-opening-for-early-dismissal>.

⁷ See, e.g., *United States ex rel. Walker v. R&F Prop. of Lake Cnty, Inc.*, 433 F.3d 1349, 1356–58 (11th Cir. 2005).

CONCLUSION

Companies should not use the Brand Memo as a justification for disregarding agency guidance. That said, the Brand Memo may be helpful to companies that are currently facing FCA actions predicated on agency guidance. In such cases, the Brand Memo may provide FCA defendants with leverage to secure a relatively favorable resolution. In future cases, defendants should be able to invoke the Brand Memo to dissuade the DOJ and private relators from bringing actions arising from noncompliance with standards set forth in agency guidance.

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