

# Client Alert

Special Matters & Government Investigations Practice Group

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## The Brand Memorandum: DOJ Restricts Reliance on Agency Guidance in Civil Enforcement Actions

On January 25, 2018, Associate Attorney General Rachel Brand issued a memorandum significantly restricting Department of Justice (“DOJ” or “the Department”) civil litigating units’ use of executive agency guidance documents in affirmative civil enforcement actions (the “Brand Memo”).<sup>i</sup> The Brand Memo outlines new policies for cases in which an executive agency previously issued relevant non-binding guidance, including:

- Reinforcing the long-standing principle that guidance documents are just that—recommendations for regulated industries;
- Emphasizing that guidance does not bind regulated parties or create new legal obligations beyond the scope of existing statutes and regulations;
- Precluding the Department from “effectively convert[ing] agency guidance into binding rules”; and
- Preventing Department lawyers from using noncompliance with guidance to establish violations of law.

This policy shift represents the latest effort by the Trump Administration to implement regulatory reform and revamp DOJ’s approach to law enforcement. Since the President signed the Executive Order Enforcing the Regulatory Reform Agenda in early 2017,<sup>ii</sup> the Department of Justice has taken several steps to minimize its reliance on enforcement through non-binding guidance. In November 2017, Attorney General Jeff Sessions, recognizing “the fundamental requirement that agencies regulate only within the authority delegated to them by Congress,” issued a memorandum significantly restricting the Department’s use of its own guidance documents.<sup>iii</sup> Critically, the Brand Memo extends that approach to guidance materials issued by other executive agencies.

This most recent change limits the use of an approach DOJ attorneys have sometimes employed to support claims and raises new challenges for the government to bring enforcement actions in regulated industries. Indeed, the Department has now made clear that it will severely restrict its use of guidance documents in False Claims Act cases,<sup>iv</sup> where the government has often relied on such materials as the basis to recover billions in settlements

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relating to alleged fraudulent conduct. In the life sciences sector in particular, DOJ attorneys have long leveraged guidance from the Department of Health and Human Services Office of the Inspector General and the Food and Drug Administration to support the government's claims. The new policy, therefore, should impact ongoing and future investigations that rely heavily on regulatory agencies' non-binding interpretations of applicable laws and regulations.

In recent years, undue reliance on agency guidance has caused the government to take positions that were proven to be erroneous. For example, in *United States v. Vascular Solutions, Inc., et al.*,<sup>v</sup> the government settled civil False Claims Act claims and then brought related criminal charges against Vascular Solutions, Inc. and its founder and then-CEO Howard Root, predicated in part on FDA guidance recommending that medical device companies obtain an updated clearance for an already-cleared device before marketing the product for a specific use that was covered by the product's general clearance. The jury fully acquitted the defendants, however, after the defense proved at trial that the company had no such legal obligation, despite the government's preferences to the contrary.

Relatedly, the Department's aggressive approach to relying on non-binding guidance has led companies to file declaratory judgment actions seeking to vindicate their constitutional free speech rights under the First Amendment.<sup>vi</sup> It remains to be seen whether the Brand Memo reduces the need for such actions.

As with any new policy, questions still remain. First, the memorandum does not clearly define all the circumstances in which the government's actions and positions would "effectively convert agency guidance documents into binding rules."<sup>vii</sup> For example, it is uncertain how the government will distinguish between using guidance to establish elements of a claim (such as intent),<sup>viii</sup> and creating a new legal obligation not imposed by statute or regulation. Will use of guidance as evidence of notice and therefore intent be the exception that swallows the rule? How will this affect DOJ attorneys' consideration of guidance documents in working up a case? At the very least, DOJ attorneys can no longer admit that they are "treat[ing] a party's noncompliance with an agency guidance document as presumptively or conclusively establishing that the party violated the applicable statute or regulation."<sup>ix</sup>

Second, the Brand Memo may have limited applicability across the Department. On its face, it seemingly would not apply to criminal prosecutions. Nonetheless, it would be anomalous, to say the least, for the rule-of-law and fair-notice principles animating the Brand Memo to apply only (or more strongly) in the civil context. Perhaps DOJ will issue a new memorandum explicitly making the substance of the Brand Memo applicable in the criminal context. Even if not, however, companies should consider the Brand Memo as they craft arguments to make to DOJ in criminal investigations.

Even though those questions remain unresolved, the Brand Memo signals a welcome return to first principles regarding following the law when engaged in law enforcement. The memorandum also provides new bases for advocacy, as the government has often sought to frame theories of liability around non-binding guidance documents. Not only will companies be able to point to the Brand Memo to dissuade line attorneys from pursuing theories of liability not clearly within statutory or regulatory text, but they will also have new avenues of appealing to Main Justice when line decisions appear to conflict with this new Department policy.

With these latest changes, companies should evaluate their policies and procedures for considering guidance from regulatory agencies to ensure that their approach is grounded in sound legal and business considerations. If you have questions regarding how this memorandum might affect compliance issues or pending or future investigations or enforcement actions, please contact John Richter, Jeff Bucholtz, Dan Sale, and Peter Cooch for more information.

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<sup>i</sup>“Memorandum for Heads of Civil Litigating Components, United States Attorneys: Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases,” from Associate Attorney General Rachel Brand, January 25, 2018, *available at* <https://www.justice.gov/file/1028756/download> (“Brand Memo”).

<sup>ii</sup> Exec. Order No. 13777, 82 Fed. Reg. 12285 (Mar. 1, 2017).

<sup>iii</sup> “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>.

<sup>iv</sup> See Brand Memo at n.1.

<sup>v</sup> See No. 5:14-CR-00926, 2016 WL 806265 (W.D. Tex. Feb. 26, 2016).

<sup>vi</sup> See, e.g., Memorandum Of Law In Support Of Motion for Preliminary Injunction, *Allergan, Inc. v. United States, et al.*, No. 1:09-CV-01879, 2009 WL 3197882 (D.D.C. Oct. 1, 2009).

<sup>vii</sup> See Brand Memo at 2.

<sup>viii</sup> The memo notes that the government may use “evidence that a party read such a guidance document to help prove that the party had the requisite knowledge of the mandate,” at least where the guidance “simply explain[s] or paraphrase[s] legal mandates from existing statutes or regulations.” *Id.*

<sup>ix</sup> *Id.*