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Justice Department Rescinds Brand Memorandum, Reopens the Door to False Claims Act Actions Based on Sub-Regulatory Guidance

By John P. Elwood and Christian D. Sheehan*

This article discusses the "Garland Memo," which, while it notes that sub-regulatory guidance is not itself law, imposes few meaningful limitations on how and when Department of Justice attorneys litigating False Claims Act actions may rely on such guidance.

Attorney General Merrick Garland rescinded the Brand Memorandum,¹ which directed Department of Justice ("DOJ") attorneys not to rely on sub-regulatory agency guidance to bring False Claims Act ("FCA") cases and other enforcement actions. Framing this move as a return to pre-Trump Administration norms, this new "Garland Memo" criticizes the Brand Memo as "overly restrictive" and a "substantial" departure from DOJ's "traditional approach" to guidance documents. The Garland Memo also announces planned revisions to the Justice Manual to align with the Department's new policy.

Although the Garland Memo notes that sub-regulatory guidance is not itself law, it imposes few meaningful limitations on how and when DOJ attorneys litigating FCA actions may rely on such guidance. If past is prologue, non-binding agency guidance will once again take center stage in FCA enforcement actions across a range of regulated industries.

BACKGROUND

Before 2017, DOJ and relators routinely relied on non-binding agency guidance documents in FCA litigation to help establish both that the defendant submitted false claims and that it acted knowingly. The Trump Administration

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¹ https://www.justice.gov/opa/page/file/1408606/download.

moved to sharply curtail that practice, first through a memorandum² issued by then-Attorney General Jeff Sessions prohibiting "improper guidance documents" that sought to bind private parties without notice-and-comment rulemaking. DOJ followed that with the better-known Brand Memo³ (named for then-Associate Attorney General Rachel Brand), which clarified the principles that should guide DOJ's use of guidance documents.

THE BRAND MEMO

The Brand Memo made clear that because "[g]uidance documents cannot create binding requirements that do not already exist by statute or regulation," "the Department may not use its enforcement authority to effectively convert agency guidance documents into binding rules," and "Department litigators may not use noncompliance with guidance documents as a basis for proving violations of applicable law." The Brand Memo further explained that guidance documents could be used only for a narrow, limited set of "proper purposes": "For instance, some guidance documents simply explain or paraphrase legal mandates from existing statutes or regulations, and the Department may use evidence that a party read such a guidance document to help prove that the party had the requisite knowledge of the mandate." DOJ codified these principles in the Justice Manual.⁴

EXECUTIVE ORDER 13891

A year later, in October 2019, President Trump issued Executive Order 13891⁵ "to require that agencies treat guidance documents as non-binding both in law and in practice." Many federal agencies, including the Department of Health and Human Services ("HHS") and the Department of Housing and Urban Development ("HUD"), subsequently issued regulations on "good guidance practices" consistent with the Executive Order.

BIDEN ADMINISTRATION ACTION

Before the ink was dry on those "good guidance" regulations, the Biden Administration on its first day in office rescinded Executive Order 13891⁶ and directed agency heads to "rescind any orders, rules, regulations, guidelines,

² https://www.justice.gov/opa/press-release/file/1012271/download.

³ https://www.justice.gov/file/1028756/download.

⁴ https://www.justice.gov/jm/1-19000-limitation-issuance-guidance-documents-1.

⁵ https://www.federalregister.gov/documents/2019/10/15/2019-22623/promoting-the-rule-of-law-through-improved-agency-guidance-documents.

⁶ https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-revocation-of-certain-executive-orders-concerning-federal-regulation/.

policies, or portions thereof" implementing it. The Administration said it was doing so because those guidance rules purportedly "threaten[ed] to frustrate the Federal Government's ability to confront" the "COVID-19 pandemic, economic recovery, racial justice, and climate change." How "good guidance" regulations could frustrate crisis response was never explained.

THE GARLAND MEMO

DOJ quickly followed suit in July 2021 with the Garland Memo and a related interim final rule⁷ amending DOJ regulations. Although the Garland Memo acknowledged the Supreme Court's admonition in *Kisor v. Wilkie*,⁸ that "an agency guidance document by itself 'never forms the basis for an enforcement action' because such documents cannot 'impose any legally binding requirements on private parties,' " it contemplates more liberal use of agency guidance than was permitted under the Brand Memo.

In fact, the Garland Memo articulates no meaningful limitation on the use of such documents, encouraging DOJ attorneys to use them in "any appropriate and lawful circumstances, including when a guidance document may be entitled to deference or otherwise carry persuasive weight with respect to the meaning of the applicable legal requirements."

While it remains to be seen how exactly the Garland Memo will affect FCA litigation, DOJ likely will not be shy about pushing its limits. At a minimum, we will likely see reliance on guidance documents like agency manuals and memoranda, program releases, and advisory opinions return to pre-2017 levels. At worst, DOJ attorneys will use the Garland Memo's reference to guidance documents that "may be entitled to deference" as an opportunity to effectively convert sub-regulatory guidance into binding law, enforceable through a FCA action.

DOJ may argue that even if a statute or regulation is ambiguous, a claim is knowingly false if the agency interpreted the statute or regulation in a way to prohibit the defendant's conduct and that interpretation merits deference. There is a strong argument that using sub-regulatory guidance in this way would be inconsistent with existing FCA jurisprudence, as it could eviscerate the bedrock FCA requirements of "objective falsity" and "objective scienter."

Those principles are important safeguards to prevent the imposition of punitive FCA liability where a defendant acts based on a reasonable interpretation of ambiguous legal requirements, even if the agency disagrees with that

⁷ https://www.govinfo.gov/content/pkg/FR-2021-07-16/pdf/2021-14480.pdf.

⁸ 139 S. Ct. 2400, 2420 (2019).

interpretation. Affording sub-regulatory guidance deference would flip these principles on their head, putting the focus on whether the agency's interpretation, not the defendant's, was reasonable. Will this become the next FCA battleground? Stay tuned.