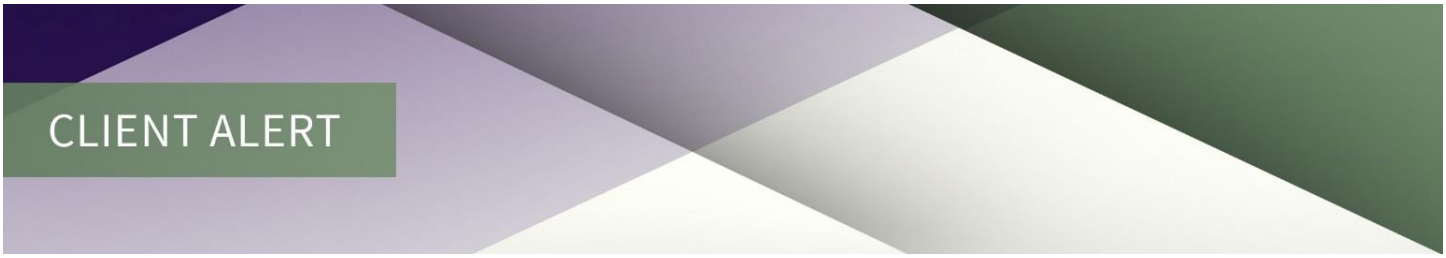

Memo Restricts Use of Sub-Regulatory Agency Guidance Documents in DOJ Cases

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On January 25, 2018, the U.S. Associate Attorney General, Rachel Brand, issued a memorandum (the "Brand Memo" or "Memo") instructing civil litigators in the U.S. Department of Justice (the "DOJ") to significantly limit their use of sub-regulatory agency guidance documents in affirmative civil enforcement matters ("ACEs"). In particular, the Brand Memo prohibits DOJ litigators from using any guidance documents to bind or "coerce regulated parties into taking any action or refraining from taking any action beyond what is required by the terms of applicable statute or lawful regulation." In addition, the Brand Memo prohibits DOJ litigators from using "non-compliance with guidance documents as a basis for proving violations of law" or "us[ing] [DOJ's] enforcement authority to effectively convert guidance documents into binding rules." The Brand Memo potentially offers significant relief to regulated companies in health care, financial services and other industries from the increasing burdens imposed by regulators through the practice of treating agency pronouncements that have not been submitted to the traditional notice and comment rule-making process as binding legal obligations.

Guidance documents are defined in the Memo as "any agency statement of general applicability and future effect, whether styled as guidance or otherwise, that is designed to advise parties outside the federal Executive Branch about legal rights and obligations." They include "Dear Colleague letters," answers to "Frequently Asked Questions," special fraud alerts, advisory opinions and a variety of pronouncement manuals and circulars issued by regulators outside the formal rule-making process. Over the past decade, such guidance documents have been used by the DOJ and relators in False Claim Act cases to demonstrate violation of federal laws or regulations.

For example, in health care litigation, the DOJ and relators in *qui tam* actions have typically relied upon sub-regulatory guidance documents from the U.S. Department of Health of Human Services ("HHS") and its agencies, including the HHS

Office of Inspector General, and the Centers for Medicare & Medicaid Services as evidence of wrongdoing by defendants. Many of these pronouncements, none of which are subject to public notice and comment before adoption, make determinations concerning what the federal government will pay for under its health programs. By coercing compliance under threat of false claims litigation, past practice turned these pronouncements into binding law.

The Brand Memo puts a stop to this practice in DOJ civil actions. In so doing, it reaffirms the fundamental separation of powers. Congress, not the Executive Branch agencies, enacts laws, and agency rule-making must be done through regular administrative procedures of public notice and comment, with congressional review, not through guidance documents and enforcement actions. As a practical matter, the Brand Memo provides a potentially powerful new tool to corporate defendants and their counsel.

While the Brand Memo permits the continued use of guidance documents as evidence of knowledge of a requisite mandate, it instructs DOJ litigators that a party's "fail[ure] to comply with agency guidance . . . does not mean the party violated those underlying legal requirements." Thus, when faced with an ACE, defendants can now more convincingly argue for dismissal of claims premised on non-compliance with the thicket of guidance issued by regulators, reducing or narrowing the scope of claims that could be pursued. And, while the Memo does not limit relators in *qui tam* actions or the agencies themselves in administrative actions, it provides useful guidance to them and removes the threat of DOJ action in such cases.

If you have any questions regarding this client alert, please contact the following attorneys or the attorney with whom you regularly work.

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