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ALERT

DOJ Rescinds Agency Guidance Policy Expanding the FCA Landscape

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After a wave of defense-friendly policies under the Trump Administration, the U.S. Department of Justice (DOJ) has reversed course on agency guidance and its buyer's remorse will enable its attorneys to try once again to bolster weak False Claims Act (FCA) cases by citing to non-binding guidance. Attorney General Merrick Garland recently rescinded purportedly "overly restrictive" policy that had "hampered" DOJ's ability to litigate cases—policy which prohibited using noncompliance with agency guidance as a basis for enforcement actions. While the "Garland Memo" acknowledges longstanding U.S. Supreme Court precedent that "guidance documents 'do not have the force and effect of law'" it paradoxically encourages DOJ attorneys to liberally cite to agency guidance in litigation. This is particularly troubling for FCA actions which tend to turn on whether defendants knowingly failed to comply with a regulation or contract provision.

Nearly five years ago, then Attorney General Jeff Sessions issued a November 16, 2017 memorandum regarding the "Prohibition of Improper Guidance Documents." That Memo barred DOJ from using its *own* guidance documents to create *de facto* obligations, standards, or rights. A couple months later, Associate Attorney General Rachel Brand expanded the prohibition for the DOJ Civil Division to *another agency*'s guidance on January 25, 2018. Importantly, the "Brand Memo" clarified that "fail[ure] to comply with agency guidance expanding upon statutory or regulatory requirements does not mean that the party violated those underlying legal requirements; *agency guidance documents cannot create any additional legal obligations*." While it did not render agency guidance completely moot—specifically allowing agency guidance as

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evidence to show intent—it certainly minimized its role in enforcement actions particularly FCA litigation. The Justice Manual § 1-20.100 subsequently incorporated this policy and expanded it to criminal enforcement in February 2018. Nearly a year later, October 2019 Executive Order 13891 further incorporated this prohibition explaining "agencies have sometimes used [their non-binding guidance] authority inappropriately in attempts to regulate the public without following the rulemaking procedures of the APA." All in, much ink has been spilled to ensure for the past five years that regulations and statutes—not non-binding agency guidance—establish the rules and underlie enforcement actions.

Nevertheless, DOJ has now explicitly rescinded its 2017 and 2018 memoranda and directed the revision of its Justice Manual. It has also entered an interim final rule addressing these changes and "revok[ing] amendments to [DOJ] regulations that were made during 2020 pursuant to Executive Order 13891." DOJ "attorneys are [now] free to cite or rely on [guidance] documents" that "are relevant to claims or defenses in litigation," even "currently pending litigation." Indeed, the Garland Memo encourages the use of non-binding agency guidance: specifically allowing reliance "when a guidance document *may be entitled to deference* or otherwise *carry persuasive weight* with respect to the meaning of the applicable legal requirements." Under this directive, DOJ attorneys will undoubtedly increase their reliance on agency guidance. But coupled with the suggestion that some guidance merits preferential treatment, the directive could cause the improper transformation of non-binding guidance into binding law.

Defendants facing FCA claims should prepare themselves for liberal agency guidance citations. Given the FDA's proclivity for "Guidance for Industry" documents, healthcare cases will likely face the realities of this new policy soonest. FCA Defendants confronted with unclear regulations or contract provisions should also expect DOJ to return to the pre-Brand Memo citations to non-binding agency guidance to bolster their arguments of false certifications.

While the Garland Memo certainly limits defendants' arguments against FCA liability, the law itself remains unchanged. As acknowledged in the Memo itself, longstanding Supreme Court precedent clearly prohibits agency guidance from "'form[ing] 'the basis for an enforcement action'' because such documents cannot 'impose any 'legally binding requirements' on private parties.'" However, Defendants may find little solace in this reality, as many will never get to the point of litigating the issue. The mere fact of an FCA investigation can prove very costly, and often those who find themselves in the FCA's crosshairs find settlement more attractive than risking even the possibility of treble damages, penalties, relators' fees and costs, their own litigation expenses, and reputational damage. As such, there exists real risk that DOJ's use of guidance documents will trigger settlements in situations where the prior administration would have likely declined intervention.

Of course, DOJ's recent internal scrutiny begs the question, is there more? Notably, the Brand Memo followed another significant policy shift—the January 2018 "Granston Memo." DOJ also incorporated this Memo on its 31 U.S.C. section 3730(c)(2)(A) dismissal authority into the Justice Manual. While DOJ has weaponized and used the Granston Memo protectively, that Memo also armed Defendants with a variety of arguments and strategies for *qui tam* disposal. Slight uptick in dismissals aside, statistics show DOJ remains conservative in *applying* its (c)(2)(A) authority. But these numbers fail to capture how often DOJ *flexes* this authority—how many

relators have voluntarily dismissed their *qui tams* when faced with the threat of a (c)(2)(A) dismissal. Indeed, perennial FCA advocate Sen. Chuck Grassley has specifically introduced the False Claims Amendments Act of 2021 to rein in DOJ's (c)(2)(A) authority. At bottom, DOJ's (c)(2)(A) authority remains at the forefront of FCA reform and jurisprudence.

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