wiley

ALERT

# The Granston Doctrine Comes to Life: *Gilead* Demonstrates the Dexterity of the Government's Dismissal Powers in False Claims Suits, but Leaves Some Questions Unanswered

December 7, 2018

Recently, the U.S. Department of Justice (DOJ) brought life to the "Granston Memo" when it told the U.S. Supreme Court of its intent to dismiss a headline-making False Claims Act (FCA) case upon remand. While this action may quiet some who have argued the Granston Memo was all flash and no cash as it simply reiterated both the statutory language of the FCA and long-standing DOJ practice, questions remain as to the government's motives and what this action could mean for FCA cases predicated on regulatory foot faults.

The case underlying this recent demonstration, *Gilead Sciences, Inc. v. United States ex rel. Campie*, is premised on allegations that Gilead misrepresented the sources and quality of ingredients for its HIV drugs when seeking U.S. Food and Drug Administration (FDA) approval. Gilead successfully argued at the district court that relators failed to plead materiality because the government continued making payments for the drugs despite knowing of allegations that the drugs did not meet manufacturing requirements. The Ninth Circuit, however, interpreted *Escobar* as requiring knowledge of noncompliance, not allegations of noncompliance, and overturned the dismissal. *Gilead* filed cert last December, and the Court invited the government to file a brief expressing its views.

## Authors

Brandon J. Moss
Partner
202.719.7554
bmoss@wiley.law

## Practice Areas

Food & Drug

White Collar Defense & Government Investigations

As expected, the government's brief asked the Court to deny Gilead's petition, arguing the relators sufficiently plead *Escobar* materiality and that the case was "a poor vehicle" to resolve this *Escobar* materiality issue. Unexpectedly – both to those following FCA jurisprudence and the relators – the government also told the Court it intends to exercise its powers under 31 U.S.C. Section 3730(c)(2)(a) and dismiss the case upon remand. Specifically, the government wrote that the DOJ had determined that the case should be dismissed "based in part on the government's thorough investigation of [relators'] allegations and the merits thereof," and that if the case reached discovery, "both parties might file burdensome discovery and *Touhy* requests for FDA documents and FDA employee discovery (and potentially trial testimony), in order to establish 'exactly what the government knew and when,' which would distract from the agency's public-health responsibilities." As likelihood of success on the merits, burdensome discovery, and distraction from agency responsibilities are all factors mentioned in January's Granston Memo, the government's decision to preview the ultimate fate of this potentially billion-dollar case to the Supreme Court is the most high-profile execution of the "Granston Doctrine" since the Memo became public.

The declaration could also be seen as a clear statement that the government's commitment to minimizing burdensome and meritless litigation does not stop at the intervention decision. If so interpreted, defense counsel may see this case as reason to continue its "lobbying" activities after declination. Conversely, the DOJ may take cues from this case and truncate its pre-intervention review, especially in light of the growing judicial pressure to unseal in a timely manner.

Similarly, the government's agency interference concerns could provide defense counsel with another possible route to dismissal. The Granston Memo advised DOJ attorneys to "consult closely with the affected agency as to whether dismissal is warranted," and seek its recommendation before filing such a request. The DOJ here seems to have adhered to the advice, albeit at a later stage in the litigation, citing concerns about burdensome discovery distracting the agency. However, the concern with minimizing the discovery burdens on agencies seems to be on a direct collision course with the type of discovery that may be necessary for a materiality determination under *Escobar*. If the government is truly committed to minimizing burdensome discovery that could detract from agency missions, the specter of deep dives into government knowledge may become a large factor in dismissal decisions – particularly when allegations revolve around regulatory foot-faults that may be common knowledge to administrating agencies.

The Granston Memo also identifies another factor for the DOJ to consider when making a declination decision: the possibility that the case could make bad law. Given the government's decision to include the modifier "in part" when describing its motivations for dismissal, the reality exists that the government's decision rests not on the rickety merits of the case or the potential for burdensome discovery, but on the case's potential to make bad law. While many covering the Granston Memo addressed the government's interest in short-circuiting cases that could make bad law right out of the gate, not many focused on the possibility that the government could use it as a shield to protect beneficial rulings, or wield it to deter *cert* and preserve circuit court precedent. As FCA litigators continue to wage war over *Escobar* and its contours, the Ninth Circuit decision stands as tremendously helpful precedent for the government and relator bar. If the government's decision to announce its intent to dismiss was "in part" motivated by its interest in preserving

law, *Gilead* would stand for the proposition that the Granston Doctrine is not limited to preservation of government resources or limiting the effects of meritless litigation on innocent companies; it can be used as a strategic weapon.

At its core, the Granston Memo aims for careful consideration where dismissal would advance the government's interests, preserve limited resources, and avoid opportunities for adverse precedent. Regardless of what motivated the government's declaration, the filing demonstrates its commitment to the factors articulated in the Granston Memo and provides an important citation for defense counsel lobbying for dismissals. Nowhere is this more true than when the allegations involve missteps in highly regulated fields and agency knowledge thereof.