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BLOG POST

HEALTH LAW SCAN

LEGAL INSIGHTS AND PERSPECTIVES FOR THE HEALTHCARE INDUSTRY

DOJ Offers Insight for FCA Practitioners at Qui Tam Conference

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The Federal Bar Association's Qui Tam Section held a terrific two-day conference in Washington, DC, on February 28 and March 1, attended by over 200 False Claims Act (FCA) practitioners presenting government, defense, and relator perspectives on current FCA practice. Shout-out to our litigation partners Wendy West Feinstein and Rebecca Hillyer who participated on a panel discussing the FCA and opioids and other pharmaceutical products, and our colleagues Katie McDermott and Jonelle Saunders who attended the program.

The keynote luncheon speaker on Friday was Civil Fraud Section Director Michael Granston from the US Department of Justice (DOJ), who did not disappoint the audience in providing keen insight on several DOJ policy issues and *Escobar* legal issues. Below is a quick summary of his comments heard from the back of the room and modest commentary on some of the points expressed.

DOJ DISMISSAL OF DECLINE QUI TAMS-JUSTICE MANUAL CRITERIA CLARIFIED

On DOJ dismissals of declined qui tams, Mr. Granston reaffirmed that DOJ will assess the potential dismissal of a qui tam that undermines or does not advance the public interest where the case is frivolous. He expressed the view that dismissals will be assessed on a case-by-case basis and will remain the exception and not the rule for declined qui tams.

Mr. Granston further clarified some of the factors in the Justice Manual such as the preservation of government resources, which alone will not justify a government dismissal unless other factors are present, such as concerns related to the merits. In assessing a potential dismissal, DOJ will look beyond the question of whether the relator can survive a motion to dismiss and assess whether the relator can prove the allegations brought on behalf of the United States. Where there is a lack of merit to the action and continued litigation harms government policies or chills benefits to patients, the government is more likely to intervene to dismiss.

FCA practitioners should now routinely review the Justice Manual criteria and DOJ dismissals to get a sense of how this new provision is working in the real world. With 80% of qui tams declined by DOJ, and years that may pass before there is an intervention decision, there remains the potential for gross inefficiencies in qui tam practice notwithstanding DOJ’s sensible position on potential dismissals of declined qui tams.

ESCOBAR MATERIALITY STANDARD IN FACE OF GOVERNMENT INACTION

On materiality issues related to *Escobar*, Mr. Granston addressed the trend in court decisions that have found government inaction as a basis to hold there is a lack of materiality – the critical element identified by US Supreme Court Justice Clarence Thomas in the *Escobar* decision.

Mr. Granston explained that the *Escobar* legal standard on materiality involves not just establishing a legal right to deny payment but also whether the alleged violation would be important to the agency decision to pay. In recognizing that government action can be a factor, however, Mr. Granston explained that it is often no surprise that the government does not take action and such lack of action is not a definitive statement of materiality. There can be good reasons to continue payment in the face of an alleged violation.

Mr. Granston identified several components of DOJ's litigation position on *Escobar* materiality related to government inaction, including

- a government failure to act is irrelevant unless there was notice of prior violations. Inaction is not otherwise probative of materiality;
- an FCA plaintiff (DOJ or relator) does not have to identify prior government action or inaction at the motion to dismiss stage, there is a presumption of materiality in the complaint allegations; and
- the materiality presumption may be rebutted at the summary judgment stage, presumably after discovery.

FCA practitioners should anticipate these points in litigation and also be on the lookout for judicial decisions that have granted dismissals at the motion to dismiss stage on the basis that materiality is not sufficiently pled.

BRAND MEMO IS NOT DEAD

It was good to hear that the Brand Memo issued for civil enforcement actions has not been deep-sixed as a matter of policy. Mr. Granston noted that a legal duty must be grounded in statute or regulation. The Justice Manual clarifies that *sub rosa* agency guidance may be used, however, to show a defendant's knowledge of standards and to assess, for example, reasonable and necessary services. The Brand Memo does not eliminate the ability of the government to rely on such agency guidance but government enforcers need to assure such reliance is not creating new law.

Well, it does sound like the Brand Memo likely will go the way of the 1998 Holder memo on civil enforcement practices but FCA practitioners should continue to make the legal distinction between law and sub rosa guidance since courts remain interested in the question of whether and when a legal duty exists sufficient to impose punitive FCA liability.

Now, how many FCA practitioners today have ever heard of the Holder guidance? Maybe DOJ will consider updating that guidance in 2019.

NEW COOPERATION CREDIT FOR CIVIL FRAUD SETTLEMENTS?

The Justice Manual reference to cooperation credit in FCA cases was also discussed by Mr. Granston, who indicated further guidance may issue in May 2019. In essence, DOJ has more flexibility to provide credit in resolving cases, including partial credit on damages. Cooperation means the DOJ may accept the defendant's calculations or discount damages. DOJ may also acknowledge cooperation in its press release. In practice, many US Attorney's Offices discount damages based on the merits and other factors, so it remains to be seen how this concept develops beyond the realities and equities of routine case assessment. It is certainly nice to have DOJ say a company cooperated in a press release, though most companies do that as a matter of course.

Tags: **Brand Memo**, **Civil Fraud Settlements**, **DOJ**, **False Claims Act**, **Materiality Standard**

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