2015 Roundtable Series

False Claims

False Claims Act practice is evolving in subtle ways that may particularly affect cases where the federal government does not intervene. Recent decisions help clarify the law's "first-to-file" rule and who may pursue allegations that entities have made false claims for government funds. Other especially noteworthy developments so far this year include the U.S. Supreme Court's ruling in *KBR v. ex rel Carter* and the Ninth Circuit's unanimous en banc ruling in *U.S. ex rel. Hartpence v. Kinetic Concepts*. Courts also have allowed plaintiffs to use extrapolation and sampling to establish liability, in addition to damages.

California Lawyer magazine met with five panelists in early July. They were Lexi Hazam of Lieff Cabraser Heimann & Bernstein; Ryan Hassanein of McKesson Co.; Mark Labaton of Isaacs Friedberg & Labaton; Stacey Sprenkel of Morrison & Foerster; and Sara Winslow of the U.S. Attorney's Office for the Northern District of California. The roundtable was reported by Cheree P. Peterson of Barkley Court Reporters.

Participants

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DISCUSSION

MODERATOR: It's unusual to have a U.S. Supreme Court ruling under the False Claims Act (FCA). How will application of the Wartime Suspension Limitations Act (WSLA) and the first-to-file bar change?

RYAN HASSANEIN: Indeed, for FCA practitioners, this was an exciting year to follow the Supreme Court. In *Kellogg Brown & Root Services, Inc. et al. v. U.S. ex rel. Carter*, 575 U.S. ___ (2015) ("KBR"), there were two issues: whether the WSLA tolls the statute of limitations applicable to FCA claims, and whether a first-filed lawsuit that is no longer "pending" bars a subsequently-filed suit. On the first, the Supreme Court ruled that the WSLA is limited to criminal offenses and thus does not apply to the False Claims Act.

Regarding the second issue, the FCA's first-to-file bar states that "no person other than the government may intervene or bring a related action based on the facts underlying a pending action." In *KBR*, the previously-filed case had been voluntarily dismissed so the Court had to interpret the word "pending." It held that "pending" means "remaining undecided" or "awaiting decision" and that the first-to-file bar is not triggered when the earlier case is no longer "pending."

That arguably invites whistleblowers to file follow-on suits based on the same facts as an earlier suit. There are, however, other defenses available in a follow-on FCA suit, including the FCA's public disclosure bar and res judicata. Remember, most courts hold that a dismissal under 12(b)(6) or under Rule 9(b) constitutes a decision "on the merits" for purposes of res judicata.

MARK LABATON: I agree that the first-to-file portion of the Supreme Court decision probably will have greater impact. And I agree this decision does not resolve some first-to-file issues. But the holding clarified that the first-to-file bar does not prevent meritorious subsequent lawsuits from going forward when the first turned out not to be viable. The intention of the bar was to encourage whistleblowers not to sit on their information and the decision was based on the language very simply in the act.

LEXI HAZAM: It's important to keep in mind that this case involved a relator who had filed two prior cases, and then there were other cases brought during intervening periods by other relators. All the prior cases had been dismissed without prejudice. In its submission to the court, the government said if you don't read "pending" in this plain-language manner to mean literally still pending, you risk turning the first-to-file bar into a draconian version of the public disclosure bar that would forever bar suits based on similar facts, even when brought by an original source, which this relator was.

STACEY SPRENKEL: There is also a recent DC Circuit decision regarding the first-to-file bar. In *United States ex rel. Todd Heath v. AT&T, Inc.*, No. 14-7094, 2015 U.S. App. LEXIS 10547 (June 23, 2015), the DC Circuit revived a relator's suit finding it was not barred by the first-to-file rule. The District

of Columbia had dismissed the case because the same relator had already accused an AT&T subsidiary of fraud in a previous qui tam action. The relator then filed this second action alleging a nationwide scheme. Both cases involved allegations of a similar type of scheme (one case relating to only a subset of the broader nationwide scheme), and both were filed by the same relator. Nonetheless, the DC Circuit has allowed the broader second-filed suit to go forward. Between *KBR* and the DC Circuit's decision in *Heath*, we have two recent decisions that seem to be narrowing the first-to-file bar.

HASSANEIN: Another interesting ruling that came out of that decision was that the first-to-file bar is not a jurisdictional defense, which is not an issue that many courts have addressed head on. Rather, most courts have simply referred to the first-to-file bar as a jurisdictional defense without conducting an analysis. After *Heath*, at least in the D.C. Circuit, the first-to-file bar must be raised in a 12(b)(6) motion, and failure to raise it then will constitute a waiver of this unique defense in FCA suits.

MODERATOR: How is the jurisprudence developing around Rule 9(b) of the False Claims Act?

HAZAM: I would start with going back to *Nathan v. Takeda*, a Fourth Circuit ruling (*U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451 (4th Cir. 2013) cert. denied, 134 S. Ct. 1759, 188 L. Ed. 2d 592 (2014). The Supreme Court declined cert in 2014, thereby forgoing the opportunity to resolve the circuit split over what is required to satisfy Rule 9(b) in an FCA case. Since that time, the jurisprudence seems to be evolving towards the more lenient standard that does not require the relator to identify specific false claims under Rule 9(b). Instead, the relator may describe the fraudulent scheme at play and put forth reliable indicia to support an inference that claims were actually submitted. Prior to the past year, the split was such that the First, Fifth, Seventh, and Ninth Circuits employed the more lenient standard, and the Fourth, Sixth, Eighth and Eleventh applied the more stringent 9(b) standard, which requires specific claims to be identified.

LABATON: And the First Circuit has moved to the more lenient standard over time. So I'm not sure the Supreme Court will need to resolve the split; the circuits could eventually sort it out among themselves. In part, the rationale for a more lenient standard is that there's an asymmetry in information and documents between the defendants and the relators.

SPRENKEL: Well, to be clear, we're calling it the more lenient standard, but the plaintiff still must meet the pleading requirements of Rule 9(b). Even in courts that don't require the relator to plead a specific claim, they still need to plead with particularity the who, what, when, and where of the fraud – enough detail to support an inference that false claims were in fact submitted.

WINSLOW: These cases tend to come up when the government declines to intervene because typically the government has access to information about the claims, while the relator often doesn't. But the rule doesn't say claims must be stated with particularity; it says the circumstances constituting fraud or mistake must be stated with particularity.

MODERATOR: How is the use of statistical sampling evolving?

SPRENKEL: Over the past year, a handful of courts have permitted the use of extrapolation and sampling to establish liability, not just damages, in FCA cases. Establishing liability through sampling might raise legitimate due process concerns. It raises unique concerns in the health care context—for example, can claims really be deemed characteristic of a broader subset of other claims if you have issues regarding whether a product or procedure is medically necessary? How can you draw a conclusion about whether a given product or procedure was medically necessary for a specific patient, given that patient's condition and medical history? A judge in the District of South Carolina just certified for interlocutory appeal to the Fourth Circuit the question of when statistical sampling can appropriately be used to establish FCA liability. (*United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 12-3466 (D.S.C. June 25, 2015)). It will be interesting to see what happens.

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> —RYAN HASSANIEN

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"Statistical sampling ... may have come back to bite the plaintiffs because the court bifurcated the case such that falsity would be heard first and separately from the rest of the case."

—LEXI HAZAM

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WINSLOW: It makes sense, as a policy matter, for courts to allow extrapolation in some types of cases. For example, a health care fraud case can have hundreds of thousands, even millions, of claims, and to prove the case claim by claim could take years. No judge is going to want that, and I don't think many are going to say, "If you commit a whole lot of fraud, you can get away with it because it's not feasible to prove it all."

HASSANEIN: There are at least two competing concerns regarding the use of statistical sampling to establish liability. On the one hand, in cases where there's a significant number of allegedly false claims, a review of every claim would significantly drain judicial resources. On the other hand, the plaintiff, be it a whistleblower or the government, bears the burden of proof as to each alleged FCA violation, and the sine qua non of an FCA violation is an actual false claim. In practice, courts seem to be taking a pragmatic approach that depends on the circumstances of the case at hand, and that's probably the right result given these two competing and legitimate policy interests.

HAZAM: One of the interesting cases on this front is AseraCare, out of the Northern District of Alabama, which allowed statistical sampling to prove falsity (*United States v. AseraCare Inc.*, No. 2:12-CV-245-KOB, 2014 WL 6879254 (N.D. Ala. Dec. 4, 2014)). It may have come back to bite the plaintiffs, however, because the court bifurcated the case such that falsity would be heard first and separately from the rest of the case. In the initial falsity phase, the court held that the government could not introduce evidence about general corporate conduct, deeming it too prejudicial to the defendants. It's one of few times a False Claims Act case has been bifurcated, if not the first time. We had to brief this in one of my cases last year, the *Office Depot* case, but the issue was never actually decided because the case was resolved. (See *State of California ex rel. David Sherwin v. Office Depot, Inc.*, Case No. BC410135 (Los Angeles Superior Court).) In that case, the defendant wanted the original source issue to be heard first, thinking that was its strongest defense. Efforts to bifurcate could become more common going forward.

WINSLOW: Well, it's a preponderance of the evidence standard. You're simply arguing to the jury that based on the expert evidence and the statistics and the extrapolation, it's more than 50 percent likely that the defendant submitted false claims. To me it's not that much of a stretch, particularly when you're dealing with tens of thousands or hundreds of thousands of claims.

HASSANEIN: Keep in mind that this issue will not come up in all FCA cases. For instance, when a defendant is accused of fraudulently procuring a federal contract, many courts hold that every claim submitted thereafter is deemed false, rendering it unnecessary to review each claim to assess liability. Where this issue has been coming up is in the health care arena, particularly in cases against providers where the allegation is that medical services or products were not medically necessary.

HAZAM: Sara, is the government finding that its perspective on experts is changing in light of these cases?

WINSLOW: In health care fraud cases involving medical records review, what we've done for as long as I've been doing these cases is to pull a statistical sample and have an expert look at the records in the sample. Often when we're in discussions with the defendant before our intervention decision, they'll do the same thing. In the settlement context, we'll be discussing whose expert is correct, whose analysis is correct, not whether somebody should have looked at each and every file.

HAZAM: So it's essentially the parties just doing in court or at trial what they would be doing in the negotiation context.

WINSLOW: That's a good way to put it.

MODERATOR: There was a key en banc hearing in a False Claims case in the Ninth Circuit this year. Can you lay out the argument there?

LABATON: One issue in *United States ex rel. Hartpence v. Kinetic Concepts* (2015 DJDAR 7881, July 7, 2015) pertains to the original source exception to the pub-

lic disclosure bar, which bars relators from proceeding with actions when there is a prior public disclosure. The original source exception at issue had two statutory requirements: the first was the requirement that the relator have direct and independent knowledge of the allegations, and the second issue was that the relator must inform the government of those allegations in advance. Twenty-three years ago, the Ninth Circuit added a third requirement making it necessary for the relator to have had a hand in any public disclosure. This requirement is not justified by the statutory language of the False Claims Act and unduly bars potentially meritorious cases. The second issue in the case was how narrow, or broad, the first-to-file bar should be. Our position is that for policy reasons, and based on a textual analysis, it should be a narrow bar. [Labaton argued the case in March and won a unanimous favorable ruling the day after the roundtable met.]

HAZAM: Mark, presumably you also argued that had the intent been to include this requirement, Congress would have made that clear.

LABATON: Yes. Nowhere in the statutory design or in the legislative history is it indicated that this was the intent of Congress. There is also a provision in the 1986 version of the False Claims Act for smaller penalties for original sources who in the eyes of the government have limited value. That language wouldn't have been in the statute if Congress intended there to be a requirement for relators to have a hand in the public disclosure.

MODERATOR: In the Northern District of California, there was the dismissal of qui tam claims brought by the Gilead employees in the *Campie* case. Where does the ruling leave those kind of claims?

SPRENKEL: In *Campie*, the court refused to allow relators to use the FCA to police activity under the federal Food Drug and Cosmetic Act. [*United States ex rel. Campie v. Gilead Sciences, Inc.*, No. 11-0941, 2015 U.S. Dist. LEXIS 1635 (Jan. 7, 2015) ("*Campie I*"); 2015 U.S. Dist. LEXIS 77261 (June 12, 2015) ("*Campie II*").]

There, two employees filed a qui tam suit against their previous employer, alleging various violations of current Good Manufacturing Practices ("cGMP") requirements. The relators claimed that these regulatory issues gave rise to FCA liability on the theory that if the FDA had been aware of them, it would not have approved the drugs at issue; as a result, relators claimed that all claims for payment submitted to Medicare and Medicaid were false under the FCA. The Court dismissed relators' claims, finding that alleging violations of cGMP requirements is not sufficient to state a claim under the FCA, because the products at issue had obtained FDA approval, and Medicare and Medicaid do not condition payment on compliance with cGMP regulations.

Then in June, the court dismissed the relators' amended complaint, which alleged a failure to obtain supplemental approval following manufacturing changes, because Medicare and Medicaid do not condition payment on supplemental approval.

WINSLOW: This is a case my office declined. But we filed a statement of interest in response to both of the motions to dismiss, so I can't talk about it. However, a general point I'd like to make is that courts often dismiss False Claims Act cases because the allegations don't fall neatly into categories like implied vs. express certification or legal vs. factual falsity. It's understandable that judges want to bring some structure to this broad law and figure out if this is a case that should proceed or a case that should be dismissed. But the False Claims Act doesn't require certification at all and it doesn't require a specific type of falsity, and I think it's problematic to focus on these categories rather than the elements of the Act itself.

HAZAM: These rulings could have implications for cases in which the fraud is a violation of a regulation from a particular agency or a misrepresentation to a particular agency that is not the payor. You have what strikes me as a somewhat artificial distinction where you can't have liability because tasks are broken down between two different agencies—the FDA is the one that's going to issue approval of your drug, whereas CMS Medicare is the one that

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"The Fourth Circuit affirmed ... that the False Claims Act should not become a 'sweeping mechanism to promote regulatory compliance.' "

—STACEY SPRENKEL

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issues the check. If there were only a single agency involved, there would be liability.

HASSANEIN: I think what's going on in cases such as Campie is that certain judges view with a great deal of skepticism the proposition that the FCA can be used as a tool to police violations of any statutory, regulatory or contractual obligation owed to the government. Indeed, just last month, the Seventh Circuit, in *U.S. ex rel. Nelson v. Sanford-Brown Ltd.*, No. 14-2506 (June 8, 2015), rejected the implied certification theory of liability—

HAZAM: Altogether.

HASSANEIN: Some judges don't view the FCA as an all-purpose fraud statute.

SPRENKEL: Late last year, the Supreme Court denied cert in a case that involved underlying allegations of regulatory violations. In *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694 (4th Cir. 2014), the Fourth Circuit affirmed dismissal of a relator's complaint alleging that his former employer had violated FDA safety regulations and held that the FCA should not become a "sweeping mechanism to promote regulatory compliance." Decisions like these make a lot of sense; otherwise, every perceived regulatory violation could turn into a possible FCA case.

MODERATOR: Switching gears, how does a $450 million settlement arise in a case the government didn't want to touch?

HAZAM: The past year has seen both huge settlements and huge verdicts in non-intervened cases, which is remarkable. In the *DaVita* case (*David Barbetta v. DaVita Inc. et al*, Case No. 1:09-cv-02175, U.S. District Court in Colorado) settled this spring for more than $400 million, and the *Trinity Guardrail* case (*U.S. ex rel. Joshua Harman v. Trinity Industries Inc. et al.*, Case No. 2:12-cv-00089, in U.S. District Court, for the Eastern District of Texas) resulted in a jury verdict of more than $500 million. So we're increasingly seeing cases that relators have continued to pursue without active involvement of the government but with spectacular results.

WINSLOW: We always say when we decline a case that it's not necessarily because of the merits. There are many reasons the government might decline a case–policy reasons, resource reasons, a whole host of reasons–that have nothing to do with the merits. Cases like this tend to prove that.

LABATON: This is another sign of the False Claims Act evolving. Now that we see more and more cases and larger and larger settlements and law firms putting substantial resources into cases, judges see that many cases in which the United States doesn't intervene do have merit. Any presumption that cases where the government declines to intervene might not have much value has diminished, and that will continue as we get more of these settlements.

HASSANEIN: A $450 million settlement doesn't mean there was any merit to the case. What it shows is—given the breadth that courts have read into the FCA's liability provisions, and given the FCA's mandatory treble damages and penalty provisions—defendants are willing to pay large settlements to avoid the significant financial and reputational risks that would accompany a loss at trial. So just as the DOJ's decision to decline intervention in a case doesn't necessarily speak to the merits, a defendant's decision to settle a case doesn't either.

MODERATOR: What are some emerging litigation strategies?

LABATON: There was a decision by Judge Jon S. Tigar in the *Siebert* case (*Gary Siebert v. Gene Sec. Network, Inc.*, 2013 WL 5645309 (N.D. Cal. Oct. 16, 2013) a little over a year ago that was helpful in limiting defendants' ability to argue that a False Claims Act relator is relying on "stolen" documents. The Ninth Circuit previously weighed in on the stolen document issue in the *Cafasso* case (*United States ex rel. Cafasso v. General Dynamics C4 Systems, Inc.*, 637 F.3d 1047 (9th Cir. 2011). Since then, Judge Tigar made it clear that it was against public policy to have confidentiality agreements that would restrict relators from using company documents to support their FCA allegations. On the one hand, relators should not indiscriminately take company docu-

ments unrelated to their FCA action and can potentially face liability for doing so. On the other hand, it would be wrong and unduly chilling to False Claims Act cases if relators were subject to penalties for taking documents that they needed to prove their case.

SPRENKEL: The Ninth Circuit has shown sensitivity to the possibility that relators can mishandle confidential documents. In the *Cafasso* case, the relator had indiscriminately downloaded around 11 gigs of data without determining whether any file was reasonably necessary to support the claim.

HAZAM: Among them were various documents that were privileged, and it's clear that's a no-no, regardless of the issue regarding whether taking the documents is in violation of the confidentiality agreement. So relators' counsel should be careful about counseling relators not to take or share any privileged documents. Any documents relators are taking should be tailored to the allegations that they're making and should not be trade secrets.

WINSLOW: From the government's point of view, we generally believe we can use whatever documents the relator brings to us, and we expect the relator's counsel to filter out privileged materials.

HASSANEIN: Can't a relator ask for these documents during discovery?

HAZAM: Well, that's among the factors that could be considered by a court. But the Catch-22 for relators is that you have to have allegations that rise to a certain level to survive a motion to dismiss under Rule 9(b). The other issue is the risk of possible destruction of documents by the defendant.

WINSLOW: Also, the relator should come to the government with more than bare allegations. We get a lot of qui tam complaints. We can't start from scratch with each one.

MODERATOR: In what new industries do you see False Claims Act cases arising?

HASSANEIN: The FCA settlements that have caught headlines in recent months and years tend to be in the government contracting space involving situations where the government has secured a most favored pricing provision by virtue of regulations, but tech company vendors less focused on those requirements have found themselves in situations where they have failed to provide the government with the best price that they make available to commercial customers.

SPRENKEL: For technology companies, this can present a real challenge, because they typically have more commercial business and less government business and may not have the well-developed compliance infrastructure that companies with higher levels of government contracting have in place.

LABATON: I think we're going to see more of those cases, particularly in California. But there's a potential for an even larger uptick in financial fraud lawsuits if Congress enhances the incentive awards to FIRREA whistleblowers. The U.S. Attorney in the Southern District of New York has brought some very large cases with both False Claims Act and FIRREA allegations, including the case against Standard & Poor's that settled for $1.5 billion.

HAZAM: The other area to watch in the financial realm is qui tam actions brought on behalf of pension funds for practices by banks or other companies providing services to these funds. For example, we've had cases of pension funds suing their custodial banks for fraudulent pricing in foreign exchange transactions. ■

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—SARA WINSLOW

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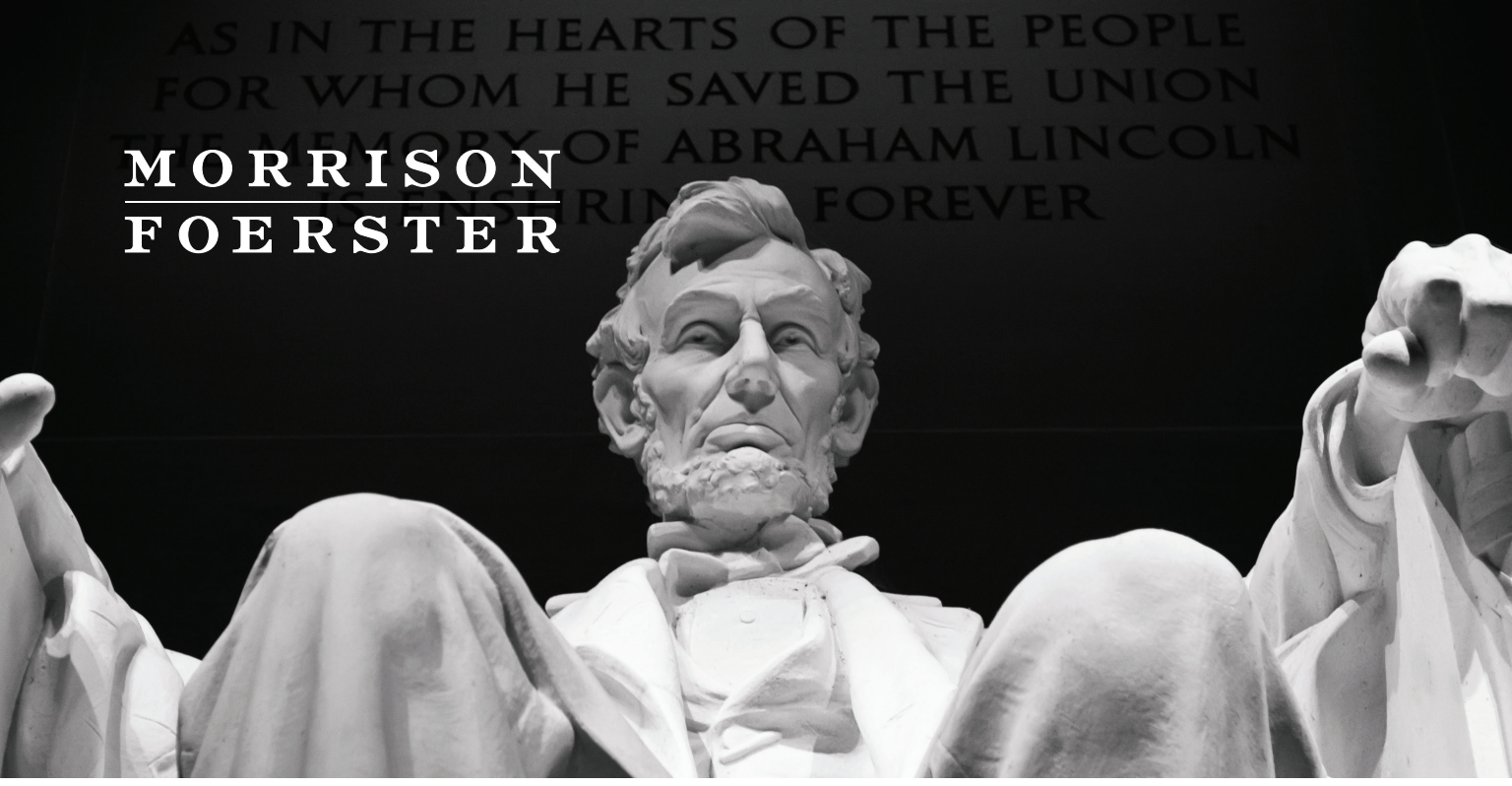

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FALSE CLAIMS ACT INVESTIGATIONS + DEFENSE PRACTICE GROUP

First passed by President Lincoln during the Civil War to penalize military suppliers for defrauding the Union Army, the False Claims Act (FCA) and its state equivalents have become the weapons of choice for the Department of Justice and Attorneys General to combat alleged fraud on the government. Led by a cross-office team of litigation and government contract attorneys, our FCA practice group has substantial experience handling FCA investigations and litigation, whether initiated by the government or by qui tam whistleblowers. We have advised a wide range of clients, from privately held companies to Fortune 50 global brands, across a broad range of industry sectors, including financial services, defense contracting and health care. We have a history of success at every stage of an FCA case and in countless jurisdictions throughout the United States. We also have wide-ranging experience handling the parallel proceedings that often accompany FCA suits, including white-collar defense, suspension and debarment proceedings, civil and criminal subpoenas, and employment and retaliation claims. We are Morrison & Foerster.

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