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## SuperValu's Lesson: Always Be Building An FCA Defense

By David Resnicoff and Andrew Patton (June 27, 2023, 4:34 PM EDT)

On June 1, the U.S. Supreme Court unanimously confirmed that scienter — the defendant's subjective state of mind — is an essential element of False Claims Act liability. In its U.S. v. SuperValu Inc decision, the court rejected a contrary view by the U.S. Court of Appeals for the Seventh Circuit, which held that subjective intent is irrelevant to the inquiry and that instead, the controlling question was whether the defendant's view of the matter was objectively reasonable.

"What matters for an FCA case is whether the defendant knew the claim was false," Justice Clarence Thomas wrote in the Supreme Court opinion. He goes on to say:

Based on the FCA's statutory text and its common-law roots, the answer to the question presented is straightforward: The FCA's scienter element refers to respondents' knowledge and subjective beliefs — not to what an objectively reasonable person may have known or believed.

On reflection, this result is not surprising. Scienter has been a bedrock theme underlying common law theories of fraud for centuries, and it is express in the statute itself. Thus, at the heart of any FCA investigation is the allegation that a material misrepresentation was made to the government in support of a claim and that the claimant knew that representation to be false.



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Under Title 31 of the U.S. Code, Section 3729(b)(1)(A), an individual can act knowingly through actual knowledge, deliberate ignorance or reckless disregard.

"Actual knowledge" is what the defendant is aware of. "Deliberate ignorance" is when a defendant avoids learning the truth or falsity of a statement, despite being aware of a substantial risk that it is false. "Reckless disregard" is when a defendant is aware of a substantial and unjustifiable risk that their statement is false but submits the claims anyway. In each case, the knowledge inquiry focuses on the defendant's state of mind at the time the claim was submitted.

In typical FCA investigations, the government gathers facts from the relator, other witnesses, documents and data, and attempts to show that rather than a mere contractual dispute, the defendant ripped off the U.S., and either knew what they were doing, didn't care or were reckless in doing so.

Sometimes the assimilated evidence supports a clear finding of knowledge. But often, the facts are not

so clear. Relators and witnesses may be biased and shape their memories to suit their interests. Emails, texts and other electronic communications inevitably tell an incomplete story. Prosecutors are left to draw conclusions from a partial picture.

Disproving an inference of nefarious intent after the fact is difficult. We suggest, however, that there are two straightforward steps that companies can take to build a record that will help preclude a finding of the requisite bad scienter under the FCA, especially where the government's view is based on deliberate ignorance or reckless disregard.

First, companies can create a decision protocol and an accompanying nonprivileged record concerning regulatory compliance and claims submission, so they can show their work and get credit for it.

Second, companies can create a compelling compliance story to pull off the shelf, review with the government and hopefully extinguish any theory of programmatic fraud.

These steps do not require reinventing the wheel. Rather, SuperValu is a reminder to double down on fundamental compliance strategies. Companies that do so will be well-armed to convince prosecutors to decline an FCA case, and be well-positioned for success in any litigation with the government or a relator.

## Recommendations

Build a decision protocol, and nonprivileged record concerning the interpretation of ambiguous and undefined contractual, regulatory and other legal requirements.

Companies providing goods and services to the government are subject to scores of contractual, regulatory and other legal requirements that may affect eligibility for payment of claims. Some requirements are straightforward on their face. Others are complicated, but easy to interpret using explicit agency guidance.

Other contractual and regulatory requirements, unfortunately, are ambiguous and have little agency guidance. This third category of requirements poses significant legal risk.

How is a company supposed to abide by requirements that are unclear on their face? And when relators surface, and the government comes calling, how can the company demonstrate the efforts it took to comply with the requirements, notwithstanding their ambiguity?

To protect against these risks, companies should identify regulatory, contractual and other legal requirements in the "ambiguous and undefined" category, and create a deliberate and memorialized process for interpreting the requirements and implementing that interpretation. That process, if necessary, can later be shared with the government.

For example, the process might work as follows, tailored to a company's own needs:

- Initial identification and review of unclear and ambiguous criteria by contract specialist or claims coordinator;
- Involvement of supervisors, compliance staff and nonlegal regulatory personnel as necessary;

- Involvement of company counsel and outside counsel, as necessary;
- Consideration of agency regulations, rules and guidance, if any, as well as evidence of industry
  practice. In the absence of guidance, request formal and informal clarification from the agency,
  keeping a record of communications;
- Determination of company position and creation of accompanying nonprivileged record that articulates the company's understanding of the requirement and, critically, the process followed and basis for the interpretation; and
- Communication and implementation of nonprivileged decision to claims function.

Ideally, the record memorializing the interpretative steps should not be privileged so that it may be shared with the government as the primary exhibit supporting that the company did not knowingly submit false claims. It should not contain any express attorney-client communications or requests for such opinions, though it may reference the fact that advice was sought.

Rather, the nonprivileged record would simply memorialize the company's understanding of the requirement at issue, the basis for that understanding and its process for compliance as an operational matter — none of which would waive the attorney-client privilege.

Indeed, the record is intended to demonstrate a deliberate, considered and good faith effort to understand and abide by the ambiguous criteria at issue. In this way, even if the government views the company's interpretation as incorrect, it is demonstrably not the result of a knowing incorrect interpretation.

Companies may also choose to create a so-called privilege package, that is, a written record of advice sought and received from counsel on a particular issue. While they need not ever disclose this advice, if push comes to shove, and the government cannot be talked out of intervention, companies may choose to share such packages with the government to head off intervention.

Lawyers and clients reflexively recoil at waiving the attorney-client privilege, but a privilege package that contains a record showing that the lawyer was provided with all relevant information and provided responsive advice, and that the advice was implemented in good faith, may be worth multiples of the fees paid to obtain it in the first place. Of course, such information would be invaluable during actual litigation and, if necessary, trial.

Even in the context of a nonprivileged decision protocol, companies may still benefit from consultations with counsel during discussions with the government about intervention. Without expressly raising an advice-of-counsel defense, a company is free to outline its reasonable decision-making process, indicate merely that advice of counsel was sought — and that it would not be shared — and that a determination had been reached.

While the government will say that it will not credit the legal advice without seeing it, the mere fact that counsel was consulted will buttress the impression of a considered and deliberate attempt to reach the proper interpretation.

A word on seeking agency guidance: Some lawyers and companies are loath to ask questions they do not want answers to, preferring instead to argue after the fact that if the company's decision was

wrong, it was because the rule or agency guidance was unclear.

When a company seeks clarification from a government agency, one of three things can happen: (1) The government's clarification is consistent with the company's intended course of action; (2) the clarification conflicts with the company's desired interpretation and the company will have to pursue a different course of action; or (3) the agency will decline to clarify, which leaves the company on its own to decide how best to proceed.

No matter the outcome, seeking clarification provides strong evidence of intent to comply and avoids relying on post-hoc rationalizations that "the rule is hard to understand," which the government always perceives as hollow.

## Build an effective compliance program tailored to the business and industry, focusing on government contracting and FCA risk.

Imagine a company that can demonstrate the hallmarks of an effective compliance program with respect to its government claims, like those outlined in the U.S. Department of Justice, Criminal Division "Evaluation of Corporate Compliance Programs," released in March. That company would have a solid foundation on which to build any defense against FCA liability.

Paired with a solid decision protocol and record, as discussed above, defense counsel would be on strong footing to argue for declination or to prevail in litigation. When subject to scrutiny, neither the government nor the typical relator will have an easy time meeting their burden to show knowledge under the FCA.

What does this look like at a more granular level?

1. Ensure the compliance program is risk based and right-sized.

The sine qua non of any effective compliance program is a sound understanding of the risks inherent in any company's particular industry. A risk assessment that addresses these questions, among others, is critical.

Here are some logical areas of inquiry:

- Regulatory Expertise. At a basic level, what are the regulatory regimes implicated by your government business? Are they well understood? Are there knowledgeable employees responsible for understanding your regulatory responsibilities, tracking evolutions in the law, and driving business change in response? What is the relevant industry best practice? Have there been compliance failures in the industry and self-assessment in response? Are there areas of ambiguity and uncertainty in the regulation, and, if so, have they been resolved? Is there a nonprivileged record of the resolution and decision and the process by which the resolution was reached?
- Government Contracts. What business components depend on government payments for their revenues? Do these business components have a good understanding of their government contracts and claims profiles? Is there an up-to-date inventory of government contracts and claims that are regularly submitted?

- Claims Process. How does the claims process operate? Are the inputs reliable, consistent and memorialized? Are the employees managing and operating that process knowledgeable? Are they sufficiently staffed? Is there a succession plan?
- Factual Assumptions. What factual assumptions underlie ongoing claims submission? Have those assumptions recently been tested against contractual and regulatory standards? Are some of those assumptions subject to challenge?
- The answer to these, and related, questions should result in the design, or redesign, of a compliance program tailored to the business. That risk assessment process, and "story," if well-done, can be Exhibit One in the company's defense.
- 2. Set the right tone on compliance for government contracts and claims.

It is easy to talk about setting the right tone at the top as a general matter. It is harder to ensure that the tone rings true throughout an entire organization and is reflected by those responsible for claiming money from the government.

To establish a culture of compliance that permeates throughout your organization, consider the following:

- Issue periodic statements at senior levels specifically about the privilege of government contracting and the importance of government contract and regulatory compliance;
- Develop materials and a mechanism to transmit that messaging through various levels of management;
- Ask managers to reserve time for discussions on current compliance issues and challenges in relevant team meetings; and
- Ask management to hold skip-level meetings to evaluate and drive compliance messaging.

Setting the right tone on compliance, and keeping a record of it, will proactively prevent at least some noncompliance, while also clearly communicating your company's honorable intentions to the government.

3. Implement policies and procedures that address government claims and reimbursement processes.

Policies and procedures addressing appropriate claims processes are another pillar in showing appropriate intent. A risk assessment should focus on policies and procedures necessary to ensure the compliant processing of government claims. Policies and procedures need to be clear, concise, understandable to nonlawyers and readily accessible.

Policies and procedures should also be easily audited to determine whether they have been implemented and are working. Further, policies and procedures should be communicated, and recommunicated, successfully.

4. Effectively train relevant employees on government contracting and claims processes.

Policies and procedures without effective training are just a bunch of paper. Meaningful and reinforced training is critical. Training should be presented through multiple media — including online and live, in large and small group formats — that can effectively target relevant audiences. A good record that shows training content, dates and audience also goes a long way to showing appropriate intent.

5. Establish a data-driven government claims auditing and monitoring program.

Ongoing auditing and monitoring is critical in the operation of an effective compliance program. Having identified the businesses, contracts and government claims at issue, companies should regularly test their claims against the regulatory and contractual standards, and their own policies that govern their government business.

Assuming sufficient resources, collecting and mining data should be part and parcel of any audit. The results of such inquiries should be tracked to closure, including any root cause analysis and remediation.

6. Create an expectation and practice that managers of government contracts will raise and resolve regulatory concerns.

One of the best ways to head off liability is through proactive measures. To do this, empower and expect that your contract managers will affirmatively raise concerns about regulatory and contractual issues. While the expectation and practice can be formal or informal, it should be well communicated, endorsed by management and aligned with the goal of decision protocols discussed above.

7. Establish systems to report, investigate and discipline wrongdoing.

Separate from the process of raising issues for resolution, effective compliance programs must include systems that govern the reporting, investigation and, where appropriate, discipline of allegations of misconduct. Allegations of regulatory and government contract noncompliance should be handled with extreme care and seriousness of purpose.

Nothing sets tone more effectively than consequences. Investigative findings, remediation and discipline should all be clearly documented. How a company behaves when the government is not looking tends to be an effective talking point when under government review.

8. Consider voluntary disclosure when warranted.

The subject of voluntary disclosure is complicated and worthy of its own article, especially in light of the DOJ's recently updated policies governing voluntary disclosures to the DOJ and the U.S. Attorneys offices.

There are many potential benefits to self-disclosure, and an equal number of downsides and risks. But, there is no doubt that a company that self-discloses potential wrongdoing signals its intention to do the right thing. By doing so, the disclosing party provides the government with a reason to give the company the benefit of the doubt.

9. Embed compliance criteria in employment and compensation practices related to government contracting and claims.

An often-overlooked component of a strong compliance program is the embedding of compliance

criteria in policies for hiring, promotion and compensation. This is especially true for employees whose job responsibilities involve government contracting and claims.

Examples of relevant policies include the performance of a thorough due-diligence search prior to hiring, a clean compliance record as a prerequisite for promotion and a claw-back mechanism that can be invoked should allegations of misconduct be substantiated. The government has recently increased its scrutiny of such policies, and this is an aspect of compliance program implementation where companies can be creative and demonstrate their good faith.

## Conclusion

While implementing memorialized decision protocols and robust compliance programs is costly, the expense is dwarfed by the scale of typical FCA resolutions, which commonly cost tens or hundreds of millions of dollars, not to mention the prospect of debarment or exclusion from federal programs. By proactively creating evidence of honorable intent, companies will be well armed to convince prosecutors to decline qui tam cases, and to defend against relators who pursue them.

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