A Guide To FCA Cooperation Credit For Life Sciences Companies

By **Greg Levine, Beth Weinman and Samantha Barrett Badlam** (June 18, 2019)

Greg Levine

On May 7, 2019, the U.S. Department of Justice issued guidelines describing when and under what circumstances it will award cooperation credit in False Claims Act matters.[1] Above all else, the new guidelines prioritize the voluntary, proactive and timely self-disclosure of "false claims."[2] The guidelines provide little detail, however, about what kind of information a company should disclose to earn cooperation credit. Nor do they offer any real world examples of actions taken by companies to earn such credit. This kind of detail is especially important when there is a significant disconnect between what the government and a company believe is a legally sound basis for a false claims action.

Beth Weinman

The False Claims Act imposes civil liability on those who cause the presentation of false or fraudulent claims for payment to the government, provided that such persons have actual knowledge of information that renders such claims false or act in deliberate ignorance or reckless disregard of the nature of such information.[3] Claims can be factually false, meaning that "the party submitting the claim supplies an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided;" in essence, the party "bills for something it did not provide."[4] Such factually false claims are easy to identify and voluntarily disclose, if they exist.

Samantha Barrett Badlam

More often than not, however, the government tries to build a False Claims Act case on arguments that claims are legally rather than factually false, based on an express or implied "false certification" theory.[5] In this context, the government must demonstrate that claims presented for payment involved express or implicit representations about a product's compliance with applicable law, without disclosing that the product was out of compliance with material statutory and regulatory requirements.[6] To do so, the government must prove that:

- A person knowingly made or caused to be made a claim for payment for a product or service to the government;
- The claim included an express or implied representation of compliance with statutory or regulatory requirements;

- The product or service did not comply with those statutory or regulatory requirements, rendering representations in the claim misleading;[7] and

- Compliance with the statutory or regulatory requirements was material to the government's decision to pay.[8]

The last of the foregoing elements, whether noncompliance with statutory or regulatory requirements is material to the government's decision to pay a claim, is often a matter of contention. With the U.S. Supreme Court having determined that the FCA is not intended as "a vehicle for punishing garden-variety breaches of … regulatory violations,"[9] there can often be significant daylight between how a company sees evidence of regulatory noncompliance and how the government views that very same evidence.

What is a life sciences company to do when it seeks cooperation credit but fundamentally disagrees with the government regarding whether the evidence the government seeks actually makes out a false claim?

In the context of investigations into payment of claims for off-label uses of drugs or devices, of which we have seen many in recent years, the government often asserts that evidence of a firm's marketing a product for unapproved uses proves that a company knowingly caused the submission of a false claim. In the drug context, a common corollary argument is that, if the unapproved use is not supported by certain statutorily identified medical compendia, the payment sought was not for a "covered outpatient drug."[10]

But more recently, the DOJ has begun to look at potential regulatory violations that are not directly tied to claims for payment and that are more traditionally enforced by the U.S. Food and Drug Administration, which has primary jurisdiction for ensuring the safety and efficacy of drugs and devices. Take, for example, an investigation into a firm's compliance with the FDA's current good manufacturing practice or reporting regulations.

Rare is the FDA cGMP inspection where the FDA does not find some fault and opportunity for improved compliance. But is every observation in an FDA inspection report (a "Form 483") evidence of a false claim? What if the noncompliance identified by the FDA has no causal link to any material product quality defect for a particular drug or device sold to the government? In such a situation, should a company volunteer to the DOJ all instances of potential cGMP noncompliance that could serve as a basis of FCA liability in order to obtain cooperation credit, even when the company does not view the information as evidence of a false claim?

Similarly, what should a company do in the context of an investigation into whether a company properly reported a drug or device adverse event or drug recall information to the FDA, when the firm does not believe that certain information was reportable? Or, if the company believes that, even assuming that it should have reported the information, the regulatory violation would not have been material to payment, but the government disagrees?

These are some of the crucial questions that the DOJ's new guidelines do not answer. Additionally, the guidelines neglect to mention the possibility that the DOJ can decline to conduct additional investigation of a case based on the information provided by a company. One way to interpret this omission is that any misconduct disclosed will necessarily lead to a DOJ investigation and possibly to further enforcement. While the guidelines encourage entities to disclose conduct that could serve as the basis for FCA liability, there may be little incentive for a company to make such a disclosure if doing so guarantees a costly and time-consuming DOJ investigation, followed most likely by some further action.

Despite these gaps in the DOJ guidance, life sciences companies may be relieved to know that admission of liability is not mandatory for receiving cooperation credit. The guidelines also describe many other forms of cooperation, such as by:

- Disclosing relevant facts and identifying opportunities for the government to obtain evidence relevant to the government's investigation that is not in the possession of the entity or individual or not otherwise known to the government;

- Preserving, collecting and disclosing relevant documents and information relating to their provenance beyond existing business practices or legal requirements;

- Identifying individuals who are aware of relevant information or conduct, including an entity's operations, policies and procedures;

- Making available for meetings, interviews, examinations or depositions, an entity's officers and employees who possess relevant information;

- Disclosing facts relevant to the government's investigation gathered during the entity's independent investigation (not to include information subject to attorney-client privilege or work product protection), including attribution of facts to specific sources rather than a general narrative of facts, and providing timely updates on the organization's internal investigation into the government's concerns, including rolling disclosures of relevant information;

- Providing facts relevant to potential misconduct by third-party entities and third-party individuals;

- Providing information in native format, and facilitating review and evaluation of that information if it requires special or proprietary technologies so that the information can be evaluated;

- Admitting liability or accepting responsibility for the wrongdoing or relevant conduct; and

- Assisting in the determination or recovery of the losses caused by the organization's misconduct.[11]

In light of the novelty and tenuousness of many of the theories by which the government has attempted to turn FDA regulatory violations into False Claims Act violations in recent years, life sciences companies that find themselves on the receiving end of a civil investigative demand or Health Insurance Portability and Accountability Act subpoena exploring possible FDA regulatory violations, and that wish to obtain cooperation credit, should consider voluntarily disclosing conduct they believe to be within the scope of the government's inquiry (reasonably construed), without admitting liability, and using the voluntary disclosure process as an opportunity to frame the narrative of the case.

In such circumstances, the focus will be on building the argument for why the conduct, even if it were to constitute a regulatory violation, would not be material to government payment decisions and therefore would not render any claims for payment legally false.

To the extent a company has good factual and legal arguments that the conduct the government views as the predicate for a FCA violation is not violative, providing the government with the types of information and assistance it seeks above, without admitting liability, should not detract from a company's ability to mount an effective defense. Indeed, in a cGMP or other regulatory investigation where facts can be complicated and nuanced, providing such information can be essential to ensuring that the government understands the circumstances completely and accurately. At the same time, it will better position the company to obtain cooperation credit in the event a settlement becomes the preferred outcome of the investigation.

The DOJ guidelines also note that DOJ attorneys will consider whether an entity has taken appropriate remedial actions in response to the FCA violation. The remedial actions referenced in the guidelines as examples include:

- Demonstrating a thorough analysis of the cause of the underlying conduct and, where appropriate, remediation to address the root cause;

- Implementing or improving an effective compliance program designed to ensure the misconduct or a similar problem does not occur again;

- Appropriately disciplining or replacing those identified by the entity as responsible for the misconduct either through direct participation or failure in oversight, as well as those with supervisory authority over the area where the misconduct occurred; and

- Any additional steps demonstrating recognition of the seriousness of the entity's misconduct, acceptance of responsibility for it, and the implementation of measures to reduce the risk of repetition or such misconduct, including measures to identify future risks.

Any FDA-regulated entity will need to have expertise in, and a commitment to, investigating and remediating instances of potential regulatory noncompliance. Even if a company disagrees with the government as to whether a particular instance of regulatory noncompliance constitutes a False Claims Act violation, when regulatory noncompliance is discovered it should be documented, investigated and remediated.

In the cGMP context, factual investigations and implementation of corrective and preventive actions will generally be mandated by FDA regulations. In other circumstances, such as in the context of marketing a drug or device for an unapproved use or failing to report required information to the agency, there may not be regulations requiring investigation and corrective action, yet a failure to investigate and follow up appropriately could itself be powerful evidence against the company.

A company that is subject to potential False Claims Act enforcement predicated on regulatory violations and that wishes to obtain cooperation credit should be willing to share with the DOJ its root cause analyses, investigations and remediation plans. By doing so, a company can improve its case for cooperation credit while providing the DOJ with information it could easily demand, or that might already be covered by the previously issued CID or subpoena. Additionally, the company should ordinarily have documented such information as part of its routine compliance program.

If a company will be providing the DOJ with information about possible FDA regulatory violations and remediation efforts, the firm should consider making a similar disclosure to the FDA at or around the same time, assuming the FDA is not already aware of the information. There are several reasons why doing so may be prudent. First, the FDA may be considering taking enforcement action based on the same or similar regulatory violations, and voluntary self-disclosure could earn the company cooperation points with the FDA, as well as the DOJ.

Though FDA lacks a formal self-disclosure and cooperation credit program, voluntary disclosure builds credibility and good will with the agency. Further, because the FDA (not the DOJ) is the regulator tasked with protecting the public health, the FDA will likely want to evaluate whether further action is necessary from a public health perspective, and a company might lose credibility with the FDA if the agency has to learn the information first from the DOJ.

Additionally, in some cases the FDA may believe that the DOJ is impinging on its regulatory authority, for example, by acting as a parallel regulator in complex areas such as cGMP compliance. In those situations, notifying the FDA may benefit the company both by building goodwill with the FDA and possibly by causing the FDA to become more involved in an investigation, which a company may prefer to interacting with prosecutors who are not regulatory experts. Beyond these particular considerations, common sense should dictate that "lack of transparency" with the FDA in such situations is likely to do more harm than good, and might have literally zero upside given the likelihood that the DOJ would eventually provide the information to the FDA anyway.

In addition, while a company may be concerned that disclosing regulatory violations proactively to the DOJ could trigger or expand an FCA investigation, the company may want to consider proactively disclosing such violations to FDA to get out ahead of a potential FDCA enforcement action. Disclosure in this context would involve a different analysis and should be carefully assessed with competent counsel. Where the circumstances present themselves, a company might provide such information in the context of an FDA establishment inspection or other ongoing FDA communications relating to the product or conduct.

In the absence of such a "natural" communication channel, the company will need to consider the particular circumstances, including the type of product, the conduct at issue, and, in many cases, the geographic location of the company. Such decisions require sufficient knowledge of the FDA's internal structure and procedures.

While life sciences companies may disagree with DOJ regarding what kinds of regulatory violations can constitute false claims, the DOJ's guidance on cooperation credit provides an opening and framework for firms to educate the DOJ and frame the narrative for any cGMP, reporting or other case based on FDA regulatory violations. In the context of ongoing FCA investigations, firms can obtain cooperation credit and build out their defenses at the same time. When making such disclosures, companies also should consider whether, when and how to share the same information with the FDA.

Greg Levine is a partner and Beth Weinman and Samantha Barrett Badlam are counsel at Ropes & Gray LLP.

[1] See Justice Manual Section 4-4.112-Guidelines for Taking Disclosure, Cooperation, and remediation into Account in False Claims Act matters. (https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.112)

[2] Notably, in the civil false claims act context, the guidelines do not require the provision of information about all involved individuals in misconduct as a prerequisite to cooperation, as first proposed in the Yates Memo of 2015. Rather, the new guidelines take their lead from comments made by Former Deputy Attorney General Rod Rosenstein in November 2018 that "the idea that a company engaged in a pattern of wrongdoing should always be required to admit the civil liability of every individual employee as well as the company is attractive in theory, but it proved to be inefficient and pointless in practice."

(https://www.justice.gov/opa/speech/deputy-attorney-general-rod-j-rosenstein-delivers-remarks-american-conference-institute-0) Thus, while identifying individuals substantially involved in or responsible for misconduct is the first of a number of "other forms of cooperation" that DOJ will consider when determining whether to award cooperation credit, it is not a prerequisite to obtaining such credit. That being said, the guidelines note that any entity or individual that seeks to earn "maximum credit" in a False Claims Act case should, among other steps, undertake "a timely self-disclosure that includes identifying all individuals substantially involved in or responsible for the misconduct."

[3] 31 U.S.C. §3729(a)(1)(A), (b)(1)(A).

[4] U.S. ex rel. Kester v. Novartis Pharmaceuticals Corp., 43 F. Supp. 3d 332, 360 (SDNY 2014) (internal quotations and citations omitted).

[5] Courts categorize FCA cases as involving either "factually false" claims (involving the failure to provide promised goods or services) and "legally false" claims (misrepresenting compliance with applicable rules or contractual requirements). See, e.g., United States v. Kellogg Brown & Root Servs., Inc., 800 F. Supp. 2d 143, 154 (D.D.C. 2011). Legally false claims further subdivide into "express false certification" and "implied false certification" cases (depending on whether the certification was made expressly in, or may be implied from, the claim for payment). Id. It is possible that a claim could satisfy the requirements of both factual and legal falsity. For instance, the same claim could arguably be legally false because the product delivered does not conform to a material contractual requirement as well as factually false because the product delivered is not the product that was purchased.

[6] See Universal Health Servs., Inc. v. U.S. ex rel. Escobar, 136 S. Ct. 1989, 2001 (2016).

[7] Escobar makes clear that in the context of implied certification cases, the claim presented must also make specific representations about the product or service that are rendered misleading by the failure to disclose violations of statutory, regulatory or contractual requirements. See id. at 1999.

[8] See Escobar, 136 S. Ct. at 1999-2001; Kellogg Brown & Root Servs., Inc., 800 F. Supp. at 154.

[9] Id. at 2003.

[10] Prescription drugs that lack FDA approval are generally not reimbursable under Medicare Part D and, thus, a claim for payment for an unapproved drug would be false under the FCA. Claims for payment for unapproved uses of approved drugs that are not compendia supported are also considered non-reimbursable for not being "covered outpatient drugs." See 42 U.S.C. §§1395w-102(e)(1)(A), 1396r-8(k)(2), (3).

[11] See Justice Manual Section 4-4.112 at p. 2. (https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.112)