

# LABORATORY ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## The Pros and Cons of Self-Disclosure: Q&A With Karen Lovitch

The Department of Justice (DOJ) in the last couple of years has actively incentivized companies to voluntarily self-disclose potential civil and criminal violations. *Laboratory Economics* recently spoke with Karen Lovitch, Chair of Mintz Levin's Health Law Practice and Health Care Enforcement Defense Practice (Washington, DC), about the pros and cons of self-disclosure.



Karen Lovitch

### What actions has the DOJ taken recently to encourage self-disclosure?

In 2023, on the criminal side, the DOJ issued a revised [Corporate Enforcement Policy](#), the United States Attorneys' Office [Voluntary Self-Disclosure Policy](#) and a [safe harbor policy](#) for voluntary self-disclosure made in connection with mergers and acquisitions. They generally incentivize companies to self-disclose potential misconduct, participate in investigations and take corrective action as soon as possible. If the DOJ is satisfied that you have done those things, then it likely will decline to prosecute. But the catch, at least on the criminal side, is you have to disclose something the government doesn't already know about.

Also in 2024, on the criminal side, DOJ published its [Whistleblower Awards Pilot Program](#), which provides monetary awards to whistleblowers who bring original information to DOJ about certain crimes that it doesn't already know about, including federal healthcare fraud offenses not covered by the False Claims Act (FCA). However, the report has to lead to a forfeiture that nets more than \$1 million for the government. This program puts pressure on companies to make quick self-disclosures because they are racing against employees who may report misconduct first.

On Sept. 23, 2024, the DOJ's Criminal Division revised its [Evaluation of Corporate Compliance Programs guidance](#), which puts further pressure on companies to ensure their compliance function is effective in application, thus maximizing the chance that a company will become aware of, and subsequently self-report, criminal misconduct.

On the civil side, back in 2019, the DOJ updated the [Justice Manual](#) to encourage voluntary self-disclosure and remediation in FCA cases. While the policy is not specific about the benefits of self-disclosure for the company reporting, settlements over the past few years seem to show that the government is inclined to lower the multiplier used to determine damages.

Under the FCA, the government can impose up to treble damages. So, if you have \$1 million in false claims, you might have to pay up to \$3 million. In cases settled without a self-disclosure, DOJ typically seeks a multiplier of 2x. But most recent settlements involving a self-disclosure seem to involve a 1.5x multiplier, so the DOJ is rewarding self-disclosure by applying a lower multiplier.

**What are the advantages of self-disclosure on the civil side?**

In a self-disclosure involving potential kickbacks, DOJ may be willing to consider a favorable alternative to calculating single damages. This approach is consistent with the OIG's self-disclosure protocol, which states that the OIG might calculate single damages based on the amount of the kickback that was paid instead of the amount of Medicare claims payments that were received. For example, if a lab disclosed that it gave a physician group \$100,000 of free equipment, and the physician group referred \$1 million in federal healthcare program business to the lab, the OIG will consider the single damages to be \$100,000 instead of \$1 million (and then would apply the multiplier to that number).

**Do you advise clinical labs to self-disclose a violation once they become aware of it?**

Labs have to work with their legal counsel and weigh the costs and benefits of self-disclosure. For example, if it's not 100% clear that you have a legal violation, you may choose not to disclose. In some cases, you may have to make admissions of fact in a settlement agreement, and you would have to be prepared to do that.