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Health Care Enforcement Reflections And Forecasts: Part 1


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Law360, New York (January 22, 2016, 3:23 PM ET) -- 2015 was a year of transition for the U.S. Department of Justice, with the installation of a new attorney general, deputy attorney general and several other high-level officials. In January 2015, Andrew Weissmann came on board as chief of the fraud section, filling a key role within the DOJ's Criminal Division, and reuniting the leadership of the Enron Task Force. (The task force initially had Leslie R. Caldwell, the current assistant attorney general in charge of the Criminal Division, and Mr. Weissmann at its helm). In March 2015, Benjamin R. Mizer became principal deputy assistant attorney general and acting assistant attorney general in charge of the Civil Division. The reorganization was completed with the installation of Sally Quillian Yates as deputy attorney general and, finally, of Loretta E. Lynch as attorney general, this past spring.

Despite the many officials in transition and the other important law enforcement challenges that the government faced in 2015, based on the cases pursued by the DOJ and its partners, health care fraud remains a top enforcement priority. Moreover, there have been policy developments that will impact health care fraud enforcement, as will, we anticipate, the DOJ's new compliance counsel. This three-part series includes a recap of these policy developments, some of the notable cases from 2015, and a forecast for what to expect in 2016.

General Developments

The Yates Memo

On Sept. 9, 2015, DOJ Deputy Attorney General Sally Quillian Yates issued a memo reaffirming the government's commitment to investigating individuals and prosecuting culpable ones, as well as formally directing its prosecutors to prioritize individual accountability when addressing corporate misconduct. Since then, there has been a lively debate regarding the significance of this development and whether it actually represents a change in policy. Time, of course, will be the best judge. In the meantime, here are the basics from the memo, as well as some additional commentary by high-level DOJ officials.

There are essentially six points in the Yates memo:

- To be eligible for any cooperation credit, corporations must provide to the DOJ all relevant facts about the individuals involved in corporate misconduct.

- Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation.

- Criminal and civil attorneys handling corporate investigations should be in routine communication with one another.

- Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.

- Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires, and declinations as to individuals in such cases must be memorialized.

- DOJ civil attorneys should investigate individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond the individual's ability to pay.

  See the Yates memo here; see also Mintz Levin Health Law and Policy Matters blog post, DOJ Issues Memo Directing Prosecutors to Focus on Individual Accountability, Sept. 11, 2015, (discussing the Yates Memo in detail).

On Sept. 10, 2015, at New York University School of Law, Yates gave a speech regarding the memo that strayed little from its text; moreover, she did not take any questions. The public head-scratching then began. Didn't prosecutors always seek to prosecute individuals? Didn't corporations that were cooperating with the government already disclose this type of information? What exactly was new here? Or, contrarily, was a new rigid standard required that corporations would be hard-pressed to meet? Was the government pulling back from its position that corporations need not waive the attorney-client privilege? Were joint defense agreements going to be feasible going forward? The questions abounded.

Later in September, at the Global Investigations Review Conference in New York, Assistant Attorney General Leslie Caldwell addressed the central tenet of the Yates memo, stating "companies seeking cooperation credit must affirmatively work to identify and discover relevant information about culpable individuals through independent, thorough investigations. Companies cannot just disclose facts relating to general corporate misconduct and withhold facts about responsible individuals. And internal investigations cannot end with a conclusion of corporate liability, while stopping short of identifying those who committed the criminal conduct." See Mintz Levin Securities Matters blog post, Assistant Attorney General Caldwell Clarifies Application of Yates Memo on Individual Accountability, Sept. 23, 2015.

Caldwell also offered some answers to practitioners representing corporations, saying "We recognize, however, that a company cannot provide what it does not have. And we understand that some investigations — despite their thoroughness — will not bear fruit. Where a company truly is unable to identify the culpable individuals following an appropriately tailored and thorough investigation, but provides the government with the relevant facts and otherwise assists us in obtaining evidence, the company will be eligible for cooperation credit. We will make efforts to credit, not penalize, diligent investigations. On the flip side, we will carefully scrutinize and test a company's claims that it could not identify or uncover evidence regarding the culpable individuals, particularly if we are able to do so ourselves." (That said, Caldwell acknowledged that sometimes the DOJ can obtain evidence that a corporation cannot.) Caldwell also remarked that the Yates memo does not change existing DOJ policy regarding the attorney-client privilege and work product protection. See id.

In October, at the Pharmaceutical Compliance Congress and Best Practices Forum in Washington, D.C., Principal Deputy Assistant Attorney General Benjamin Mizer of the Civil Division provided his thoughts on the Yates memo. In the context of "current law enforcement efforts that may bear on what the future holds," he focused on a few of the above bullet points. He bluntly paraphrased the first bullet point by saying "this means no partial credit for cooperation that doesn't include information about individuals," and stressed that it applies with equal force to civil investigations and specifically to False Claims Act investigations.

Mizer also emphasized that the DOJ's Criminal and Civil Divisions would focus their investigations on individuals from the outset and that criminal and civil attorneys "have been directed to cooperate [with each other] to the fullest extent permitted by law at all stages of an investigation." The latter is a point that Caldwell made early in her tenure during a speech at a Taxpayers Against Fraud conference. It was at their September 2014 conference that she announced a procedure whereby qui tam complaints would be shared by the Civil Division with the Criminal Division as soon as the cases were filed and that the attorneys in the Fraud Section of the Criminal Division would immediately review them to determine whether a parallel criminal case should be brought. See Mintz Levin Securities Matters blog post, Principal Deputy Assistant Attorney General Mizer Sheds Additional Light on Individual Accountability and the Yates Memo, Oct. 23, 2015.

It might be the case that the Yates memo is, as advertised, a memo to DOJ criminal and civil attorneys directing them to coordinate better among themselves: to amass a complete body of evidence of corporate and individual wrongdoing; to require all available evidence that corporations have regarding their employees' misconduct before awarding cooperation credit; and to obtain supervisory approval and maintain records of actions to best ensure that the procedure is uniformly applied. If such an approach is followed across DOJ and all U.S. Attorneys' offices, we may see more parallel criminal and civil fraud cases against health care providers and product manufacturers.

DOJ's Hiring of Compliance Counsel

In November 2015, Caldwell continued to emphasize the importance of companies having compliance programs fine-tuned to their specific risks, as a hedge against fraud and abuse. She specifically addressed the way the DOJ thinks about compliance programs. See Justice News, "Assistant Attorney General Leslie R. Caldwell Speaks at SIFMA Compliance and Legal Society New York Regional Seminar," Nov. 2, 2015.

Caldwell stated that when the DOJ prosecutors are considering whether to charge a corporation criminally, they "look closely at whether compliance programs are simply 'paper programs' or whether the institution and its culture actually support compliance. We look at pre-existing programs, as well as remedial measures a company took after discovering misconduct — including efforts to implement or improve a compliance program." See id.

On Nov. 3, 2015, the Criminal Division added a resource for evaluating compliance programs with the hiring of Hui Chen as compliance counsel for the Fraud Section. Caldwell addressed this addition in her remarks at the Securities Industry and Financial Markets Association conference, noting that the DOJ wanted "the benefit of the expertise of someone with significant high-level compliance experience across a variety of industries." (Previously, Chen was global head of anti-bribery and corruption at Standard Chartered and assistant general counsel at Pfizer focusing on compliance.)

In the context of making charging decisions, compliance counsel "will help [the DOJ] assess a company's program, as well as test the validity of its claims about its program, such as whether the program truly is thoughtfully designed and sufficiently resourced to address the

company's compliance risks, or essentially window dressing." Id. Additionally, compliance counsel "will help guide fraud section prosecutors when they are seeking remedial compliance measures as part of a resolution with a company." The idea is to require an effective program without being unduly burdensome. Id.

Caldwell specifically addressed speculation in the legal community that the hiring of compliance counsel was a precursor to a compliance defense. She said it is not, and that review of a company's compliance program will remain one of the several factors (i.e., the Filip factors) reviewed when the DOJ considers whether to charge a company. Id. Caldwell drove home the importance of compliance, stating "[o]ur hiring of a compliance counsel should be an indication to companies about just how seriously we take compliance." Id.

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