Deputy Attorney General Monaco Announces Additional Measures Targeting Corporate Criminal Conduct: The Impact for Life Sciences Companies

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In a speech on September 15, 2022, Deputy Attorney General (DAG) Lisa Monaco announced several important updates to the U.S. Department of Justice's (DOJ's) approach to investigating and prosecuting corporate crimes. These remarks underscore key points from a DOJ memorandum that was also issued on September 15, 2022, "Further Revisions to Corporate Criminal Enforcement Policies Following Discussions with Corporate Crime Advisory Group" and supplement the well-publicized DOJ memorandum issued a year earlier, in October 2021, "Corporate Crime Advisory Group and Initial Revisions to Corporate Criminal Enforcement Policies." Taken together, DAG Monaco's remarks and the memoranda herald a number of shifts in DOJ enforcement priorities, including a renewed focus on individual prosecutions and enhanced scrutiny of prior corporate misconduct.

DAG Monaco's September 15 speech highlights five areas where DOJ has made policy changes intended to hold individuals and companies accountable for wrongdoing and encourage good behavior:

- Individual accountability
- Prior corporate misconduct
- Voluntary self-disclosure
- Compensation incentives
- Independent compliance monitors

DAG Monaco described these policy changes as a "combination of carrots and sticks" intended to empower corporate leaders to make a "business case for responsible corporate behavior."

Key Takeaways

- DOJ continues to focus on individual accountability, which it identifies as its "first priority" in corporate criminal matters, and promises to seek individual resolutions before or at the same time as a corporate resolution. To this end, DOJ intends to reduce or deny cooperation credit for companies that engage in "undue or intentional delay" in producing information or documents. Given the low threshold for bringing criminal actions against individuals under the Food, Drug and Cosmetic Act (FDCA), DOJ's continued focus on individual accountability creates particular risk for employees and executives of life sciences companies.
- DAG Monaco provided granularity on how DOJ intends to weigh types of past misconduct in determining an appropriate resolution, which presents a particular risk area for life sciences companies given the number of enforcement proceedings brought against pharmaceutical and device manufacturers. DAG Monaco laid out an exception for acquired entities with troubled compliance histories, *if* the issues have been "promptly and properly" remedied by the acquiring company. Exactly how DOJ will apply this standard remains to be seen, and will be of keen interest to life sciences companies given the volume of corporate transactions in this space.
- All DOJ components that prosecute corporate crime are now required to maintain and publicize a policy on voluntary self-disclosure. Absent aggravating factors, DOJ will not seek a guilty plea *if* a company "voluntarily self-disclosed, cooperated, and remediated misconduct" nor require an independent compliance monitor *if* a company has "implemented and tested an effective compliance program." Given the significant carrots DOJ is offering for voluntary self-disclosures, strong consideration should be given to this key strategic decision when an issue first arises. This is particularly

important for life sciences companies, where certain criminal resolutions carry the risk of exclusion from participation in federal health care programs.

- The design of a corporation's compensation system — including disincentives to discourage misconduct and incentives to encourage compliance — will be a key metric used by prosecutors to assess a company's commitment to fostering a culture of compliance. While these types of measures have become common among life sciences companies subject to Corporate Integrity Agreements, other companies may wish to consider implementing such measures.

Key Changes to DOJ's Corporate Criminal Enforcement Policies

Individual Accountability. Given the importance of speed for conducting effective investigations, particularly of individuals, DOJ will reduce or deny cooperation credit for companies that engage in "undue or intentional delay" in producing information or documents. DAG Monaco advised that a company's "first reaction" upon discovery of key information should be to notify prosecutors. Separately, DOJ prosecutors will seek individual resolutions before or at the same time as a corporate resolution. Given that companies are often eager to bring investigations to a close as rapidly as possible, DOJ's stated intention to resolve any investigations of individuals at the same time as the corporate resolution may produce tactical tension between the company and those individuals.

Prior Corporate Misconduct. In response to feedback from the October 2021 memorandum, DOJ has provided additional guidance on how DOJ will evaluate historical misconduct. DOJ will afford the most significance to criminal resolutions in the United States and conduct involving the same personnel or management as the current matter, with less emphasis on dated conduct — defined as criminal resolutions more than 10 years and civil or "regulatory resolutions" more than five years before the current conduct. In assessing prior misconduct, DOJ advises that corporations will be expected to produce a list and summary of all such prior resolutions (with "regulatory resolutions" defined as pre-trial regulatory enforcement actions). Prosecutors also will evaluate if the current conduct shares the same root causes and, for companies operating in highly regulated industries, how a company's history compares to its peers. Notably, DOJ does not want to "discourage acquisitions that result in reformed and improved compliance structures," so companies will not be treated as recidivists if they acquire entities with historical compliance problems as long as those issues are "promptly and properly" addressed after the transaction. Finally, DAG Monaco explained that "multiple, successive" nonprosecution or deferred prosecution agreements will be disfavored and will be subject to review by DOJ leadership.

Voluntary Self-Disclosure. DAG Monaco explained that DOJ intends to "reward those companies whose historical investments in compliance enable voluntary self-disclosure and to incentivize other companies to make the same investments going forward." To this end, DOJ will require all prosecutorial DOJ components to implement formal, documented self-disclosure programs based on common principles. For example, absent aggravating factors, prosecutors will not seek a guilty pleas when a company has "voluntarily self-disclosed, cooperated, and remediated misconduct," and DOJ will not require an independent compliance monitor for such companies if they have "implemented and tested an effective compliance program." DAG Monaco closed this portion of her remarks by stating that resolutions in the near future will reaffirm that companies receive better results after voluntarily self-disclosing.

Corporate Culture. DAG Monaco emphasized the need to both adequately fund a compliance department and develop a compliance-oriented corporate culture. One way prosecutors will evaluate a company's compliance program is by examining whether its compensation system includes appropriate deterrence measures — *e.g.*, clawback provisions or escrowed compensation — as well as incentive measures, such as affirmative metrics and benchmarks to reward pro-compliance behavior. The DOJ Criminal Division will develop further guidance on this topic by the end of 2022.

Independent Compliance Monitors. To address concerns about the role of compliance monitors, the September 15 memorandum includes guidance for prosecutors on selecting and overseeing monitors to ensure, as DAG Monaco noted in her remarks, that "the scope of every monitorship is tailored to the misconduct" and to the company's "related compliance deficiencies." DAG Monaco further acknowledged that DOJ has an obligation to "stay involved and monitor the monitor."

Implications for Life Sciences Companies

DAG Monaco's speech yesterday and subsequent memorandum make clear that DOJ continues to be concerned about corporate crime, especially repeat offenders, and that DOJ is committed to holding individuals accountable. To that end, DOJ will now seek to resolve or address individual liability at the same time corporate charges are resolved, thus trying to address the complaints of many that individuals are rarely held accountable, even in instances of significant corporate misconduct. Companies and individuals that are repeat offenders will pay a higher price as a

result. And to receive cooperation credit, DOJ has emphasized that a company must affirmatively cooperate: Evidence must be provided quickly, key documents should be surfaced to the government right away and there should not be undue delays for strategic reasons, *i.e.*, no slow-walking an investigation for strategic gain. DOJ clearly is seeking to apply pressure to move investigations along more quickly, particularly those of individuals, and to better coordinate company and individual liability decisions. In response, life sciences company counsel conducting internal investigations should redouble efforts to make sure that individuals understand (through *Upjohn* warnings or otherwise) how collected information may be shared with the government. Companies also should continue to closely monitor DOJ enforcement actions to better understand what types of cooperative efforts DOJ will view as sufficient for receiving cooperation credit going forward.

But that is only part of the headline. The other part is that DOJ is focused on development of compliant culture as the antidote to corporate crime. This means establishing robust internal compliance systems and policies of self-disclosure. In particular, moving forward, a key corporate culture metric for DOJ will be financial accountability. DAG Monaco encouraged adoption of polices that use salaries, bonuses, escrows and clawbacks to incent good behavior through financial reward and sanction bad behavior with financial penalties for misconduct. It is critical that life sciences companies rededicate themselves to ensuring that their compliance programs are fully developed, implemented and pressure-tested to confirm that they are functioning effectively and working to surface issues when they arise.

All of this means that companies — and executives — seeking to avoid penalties would do well to implement overlapping, demonstrably effective systems to establish and enhance a culture of compliance. This will further challenge companies to confront practical issues of implementing and enforcing their compliance programs, not just in terms of issuing policies and providing training, but also following through to ensure that effective steps are taken when issues arise. For example, companies must grapple with employees' use of personal devices for work activities and how they can access and preserve such data if needed. Further, if problems occur, DAG Monaco's remarks make clear that companies must address the root cause. While her remarks relieve the concern that DOJ will focus on regulatory violations (such as FDA warning letters) in evaluating a company's prior history of misconduct, it is clear that recidivism will heighten the likelihood of prosecutions or monitors, and recidivism without systems of control in place could spell personal liability for executives as well as companies.

The message is clear that DOJ is concerned about corporate malfeasance and the culture that allows it, and executives at these companies are in the crosshairs. DOJ wants to place the onus on them — personally — to establish the systems and culture necessary to make compliance lapses the exception, not the rule. This, in turn, carries particular risks for life science company executives, given the low burden for individual prosecution under the FDCA.

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