

## **Battle Weary Life Sciences Industry Put on Notice: Department of Justice Targets Big Pharma and Medical Device Companies for Anticorruption Prosecutions**

**November 16, 2009**

On November 12, the Justice Department's Assistant Attorney General for the Criminal Division, Lanny Breuer, issued a stern warning to the life sciences industry and its executives. As the country wrestles with the challenges of healthcare reform, the Department is renewing its focus and coordinating its vast investigative resources to target companies and individuals in the industry who violate the law—in particular, domestic and extraterritorial anticorruption laws.

Although the crux of AAG Breuer's comments were not necessarily new, his admonition could not have been more direct—the life sciences industry, which has been under siege in recent years by federal and state regulators as well as congressional oversight committees and legislators, continues to have a bullseye on its back. The rationale for targeting the life sciences industry is due not only to the extensive profits it generates outside of the United States and the intense competition among companies, but also because pharmaceutical and medical device companies tend to come into contact more often with government officials, are highly regulated and, thus, are at a higher risk for problems. Combined, these factors create the “perfect storm” and an inviting mark for investigators.

AAG Breuer's speech did offer important insights on the Department's approach, including:

- The Department will increase its focus on rooting out bribery of foreign officials through application of the Foreign Corrupt Practices Act (FCPA) across the industry.
- The Fraud Section, which is responsible for FCPA prosecutions, is working closely with an enlarged squad of FBI agents dedicated to FCPA investigations, the Department's health care fraud unit, the SEC's new FCPA unit, and foreign regulators to maximize its ability to effectively enforce the law—both foreign and domestic.
- To achieve deterrence, the Department intends to pursue cases not only against companies, but also against individuals who will face jail time. During his speech, AAG Breuer made it clear that the Department is affirmatively targeting individuals in life sciences companies, saying “I don't care if you're a physician and I don't care if you're the clerical worker. It has to do with what you do. But if you do it, your M.D. degree is not going to be a shield.”
- Where appropriate, AAG Breuer emphasized the Department's intent to prosecute senior executives, pointing to the prosecution of KBR's former Chairman and CEO, who recently

pled guilty and agreed to a seven-year prison term. AAG Breuer also highlighted the government's successful prosecutions this summer of Frederic Bourke, Congressman William Jefferson, and Patricia and Gerald Green.

- The Department will continue to define the term “foreign official” very broadly to include not only health ministry and customs officials but also “doctors, pharmacists, lab technicians and other health professionals who are employed by state-owned facilities.” AAG Breuer stated that “it is entirely possible, under certain circumstances and in certain countries, that nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product in a foreign country will involve a ‘foreign official’ within the meaning of the FCPA.”
- Companies must have effective and “rigorous” FCPA compliance programs that are “faithfully enforced.”
- Companies that discover violations should consider voluntary disclosure of the violation, cooperation with the government, and remediation in exchange for “meaningful credit” and “meaningful benefit” for the disclosure. In closing, AAG Breuer stated: “We are fully aware that internal investigations and remedial measures may be costly. But the costs of not doing the responsible thing can be much higher—including significant criminal fines for the corporation, unwanted negative publicity, a potentially devastating impact on stock prices, and possible exclusion from Medicare and Medicaid.”

The entire speech can be found at <http://www.mainjustice.com/2009/11/12/criminal-division-chief-breuers-fcpa-pharma-speech/>.

### **Practically speaking, what should affected companies take away from AAG Breuer's speech and how will it impact the life sciences industry?**

Based on our experience counseling and handling investigations on domestic and international issues in the life sciences industry, we anticipate the following:

- The focus of federal and state regulators on the industry will continue, but it will be more closely coordinated and tougher to defend. In particular, the Department is drawing on its extensive experience investigating the operations of healthcare companies, as well as specialized expertise in FCPA prosecutions, to proactively target misconduct. We anticipate that companies will see broader investigations and indictments that include not only allegations of foreign bribery under the FCPA, but also allegations of commercial bribery under the Travel Act, and domestic inducements that violate the Anti-Kickback Statute.
- Companies that wind up in the crosshairs of a government investigation will find it harder to resist the government's settlement demands, due to the stiff penalties available under each of these statutes as well as the government's increasing willingness to use the threat of debarment and exclusion. At the same time, companies must be wary of caving in to government demands altogether due to the increased threat of parallel civil, state, and international enforcement actions, and likely follow-on shareholder and class action litigation.
- Although the government has long espoused the importance of implementing effective compliance programs, it has shown its willingness to put teeth behind that statement. Two cases this summer demonstrate the potential implications for senior management, directors, and

investors.

- In *United States v. Bourke*, the Department successfully prosecuted an investor for bribes paid by his co-investor on the theory that he “knew or should have known” the bribers were being paid. Bourke did not pay or authorize the bribes, but following the verdict, one juror stated the following in support of the verdict: “We thought [Bourke] knew [about the bribery] and definitely could have known. He’s an investor. It’s his job to know.”
- In a settlement filed by the SEC against a vitamin manufacturer and marketer and two officers, the government charged the officers based on a “control person” liability theory under Section 20(a) of the Securities Exchange Act—in other words, the SEC alleged that the officers, in their capacity as control persons, violated the books and records and internal controls provisions of the securities laws in connection with the Brazilian subsidiary’s alleged bribes.

### What can companies do to limit risk of such investigations?

- **Review domestic and foreign anticorruption-related policies, procedures, and training.** Will they stand up to government scrutiny? Do they sufficiently control risk in your organization? Do they require adequate due diligence for M&A transactions, investments, and other third-party relationships? Do they require monitoring of ongoing third party relationships? Are senior management and board members sufficiently attuned to anticorruption risks? If policies and procedures require approvals, are approvals in fact being sought?
- **Understand your risks.** Review your company’s “touch points” with foreign officials overseas. Where is your company regulated? To what extent and in what contexts do your employees come into contact with employees of state-owned or state-controlled entities?
- **Conduct periodic compliance assessments.** Risks change as company operations expand, contract and shift in a global economy. Assessments conducted two years ago may not necessarily flag the actual risks of today’s business—particularly operations that have been acquired or outsourced (but certain control/oversight remains).
- **Avoid successor liability.** Does the company seek to identify problematic conduct in due diligence pre-acquisition, or does it simply implement appropriate policies and procedures after the fact? If the latter, has the company conducted an audit to ensure that no troubling conduct is ongoing? Companies that fail to discover risks in pre-deal due diligence are at increased risk for prosecution. Companies that fail to stop problematic conduct post-acquisition are almost certain to face higher penalties if the government investigates.
- **If troubling sales activities are discovered in your company’s operations in the United States, review the same activities overseas.** The government is looking to leverage off of and expand domestic anti-kickback cases into global anticorruption cases. This has been a successful tactic in recent years and will most certainly continue.
- **Review and monitor any sales, marketing, or other activity that could be viewed as a possible “inducement” to commercial or government entities or individuals.** In particular,

companies should continue to have strict rules and oversight over, for example, the payment of commissions, consulting fees, promotional payments, travel, entertainment, meals, rebates, discounts, customer incentives, charitable donations, leasing of equipment, honoraria, grants, and of course, cash payments. This is one of the first places that the government will look for indications of improper payments or inducements.

- **Take potential whistleblower claims seriously.** If an employee raises concerns regarding overseas bribery, pay close attention to him or her—because the government will. Such concerns should touch off at least some review that will either corroborate or discredit the allegation and if problems are noted, should at the very least result in swift remedial measures.

These are just some of the important takeaways for life sciences companies and their executives as they navigate their way through this most recent wave of enforcement. As the government becomes increasingly sophisticated in its approach to anticorruption compliance enforcement, so too must the industry.

Morgan Lewis is well positioned to help prepare your company to meet the challenges ahead. Drawing on nationally recognized fraud and abuse and corporate investigations lawyers, we have the experience, depth, and knowledge to guide your company in assessing compliance risks, reviewing and strengthening compliance programs, evaluating due diligence in third-party transactions, and responding to global anticorruption investigations and U.S.-centered healthcare investigations.

If you have any questions regarding any of the issues discussed above, please contact any of the following Morgan Lewis attorneys:

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