

Public Company Alert

BUSINESS LAW DEPARTMENT

PUBLIC COMPANY PUBLICATIONS

SEC ENFORCEMENT CHIEF CAUTIONS PHARMACEUTICAL INDUSTRY ON FCPA, FDA-RELATED DISCLOSURES AND INTERNAL FINANCIAL CONTROLS

Recently, the Director of the SEC's Division of Enforcement, Andrew Ceresney, spoke about the Enforcement Division's ongoing areas of scrutiny most relevant to pharmaceutical and life science companies at CBI's Pharmaceutical Compliance Congress on March 3, 2015. These areas include compliance with the Foreign Corrupt Practices Act, corporate disclosures relating to interactions with the Food and Drug Administration and the SEC's internal controls and financial disclosure requirements. In his remarks, Mr. Ceresney offered several suggestions for avoiding or reducing civil and criminal liability at the corporate and personal levels, which are summarized below.

FCPA. Mr. Ceresney confirmed that the Enforcement Division remains "particularly focused" on the pharmaceutical and life science industry, which is a "high-risk industry for FCPA violations because of the multitude of contacts that pharmaceutical representatives regularly have with foreign doctors, hospitals and administrators." He described the principal types of FCPA misconduct as "pay-to-prescribe" bribes, bribes to get drugs on an approved list or formulary, and bribes disguised as charitable contributions. He also stressed that the Enforcement Division takes "an expansive view" of the FCPA prohibition on giving "anything of value," including non-cash items, to a foreign person to induce official action to obtain or retain business.

Mr. Ceresney urged companies to adopt strong FCPA compliance programs that are based on comprehensive risk assessments and "extensive" policies, procedures and personnel that address internal and external risks. He specifically discussed diligence and financial controls that focus on third party agents and business partners. He also reminded his audience that the SEC's whistleblower program has changed the enforcement environment, placing a much higher premium on early and active self-reporting and cooperation by companies. According to Mr. Ceresney, penalties may be reduced for cooperation and, conversely, the consequences for companies are worse when the SEC finds the violations on its own rather than through self-reporting.

FDA-Related Disclosures. Mr. Ceresney also highlighted several recent Enforcement Division actions based upon disclosure failures regarding company communications with the FDA. These cases all relate to situations in which the companies and their executives distorted the true nature of their interactions with the FDA, according to the SEC. Mr. Ceresney stated that "[y]ou need to be completely accurate in recounting your dealings with

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the FDA. So much turns on those interactions and not being straight with investors will have significant consequences.” Mr. Ceresney suggested that disclosure of the correspondence between companies and the FDA could eliminate the issues and asked companies to consider this type of disclosure in appropriate circumstances.

Internal Financial Controls. The Enforcement Division has also renewed its focus on financial reporting violations and fraud. Mr. Ceresney discussed the importance of internal controls and appropriate financial disclosures. Highlighting a sharp increase in enforcement actions and investigations during the last year, Mr. Ceresney said that the Enforcement Division focuses not only on issuers and their executives and financial personnel but also on gatekeepers, such as auditors. One of the recent trends in SEC enforcement activity is bringing charges against companies and executives based on internal controls charges even where no fraud has occurred.

Speaking about the involvement of senior management and audit committees in implementing and supervising internal controls and compliance procedures, Mr. Ceresney said:

What kinds of takeaways do we have from these cases so far? What kinds of practice pointers for how to avoid these issues? Well, in cases we have brought, we see controls that were not carefully designed to match the business, or that were not updated as the business changed and grew. And we see that senior leadership was not asking the tough questions – and sometimes not even asking the easy questions. Senior management in some cases was just not engaged in any real discussion about the controls. As a result, employees did not properly focus on them and the firm and its shareholders are put at risk.

So my key takeaway is that senior leadership of companies should place strong emphasis on the importance of designing and implementing strong internal controls. Senior officers need to ask questions about what they are being told about their internal controls – but perhaps more importantly, ask questions about the things that are not being reported to them. Dropping those occasional inquiries into conversations where they won’t be expected sends a powerful message that you want these issues to be on your employees’ minds. And what is needed is not just involvement from senior leadership but also from the audit committee. Instead of a check-the-box mentality, it is important to use careful thought at the outset to how controls should be designed in light of a firm’s business operations.

Take-Aways. With the Enforcement Division’s recent record and Mr. Ceresney’s speech in mind, we recommend:

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- Companies should be aware of the importance of adopting, and continually and thoroughly assessing the effectiveness of, their internal controls and compliance procedures.
- A strong compliance program should be tailored to a company's specific needs, risks and challenges, and will generally include compliance personnel, extensive policies and procedures, training, vendor reviews, due diligence on third-party agents, expense controls, escalation of red flags, and internal audits to review compliance.
- Senior management and the audit committee in particular should be actively involved in compliance efforts on an ongoing basis – in Mr. Ceresney's words, engaged in real discussions and asking tough questions.
- Companies should remember that these concerns are not limited to FCPA compliance: recent SEC enforcement actions have involved cases as diverse as Section 16 reporting, MD&A disclosure, Form 8-K reporting and pure internal controls failures. Mr. Ceresney's advice on internal controls and compliance applies across all parts of a company's business, controls, compliance and disclosure activities.

We recommend that you contact your regular Goodwin Procter attorney about questions involving disclosure, internal controls and the FCPA. In addition, Goodwin Procter's Securities Litigation and White Collar Defense group has extensive experience working with companies, their boards, and senior management on FCPA compliance and investigation matters. They have prepared a set of FCPA protocols and educational tools that they can customize to companies' individual scenarios.