Skadden

A Window to the U.S. – Developments in Health Care and Life Sciences Investigations, Enforcement and Litigation, and the Effects on Transactions

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Webinar Takeaways

On May 7, 2013, Skadden hosted a webinar to provide insights into U.S. government enforcement and related civil litigation for pharmaceutical and medical device companies with European operations. The webinar provided participants with practical strategies for assessing risks stemming from whistleblower complaints, government investigations and litigation, including approaches to successfully managing these risks in corporate transactions.

False Claims Act Developments & Impacts of Recent Litigation

Greg Luce | Washington, D.C.
Michael Loucks | Boston

In recent years the U.S. Department of Justice (DOJ) has aggressively used the False Claims Act (FCA) to generate billions of dollars in health care-related recoveries. Panelists highlighted that the vast majority of these recoveries are the result of settlements, many of the government's theories of liability remain untested in court and the price of settlement continues to rise.

- In the face of increasingly novel and attenuated theories of liability, companies are more inclined to go to court. A string of recent decisions in the U.S. Courts of Appeal and district courts have demonstrated that the government's most aggressive theories of liability may not withstand judicial scrutiny.
    - Truthful, non-misleading speech is not evidence of intent to introduce a misbranded drug into interstate commerce. Prosecution of sales representatives for speech was held to be an impermissible violation of the First Amendment. *U.S. v. Caronia*.
    - In several recent cases the government has failed to furnish a sufficient quantum of evidence to satisfy its burden of proof. For example, in *U.S. ex rel. Liams v. Renal Care Group*, allegations of intent to take advantage of loopholes in the Medicare regulatory scheme to make a profit was insufficient to sustain a claim absent evidence of violative behavior.
    - An appellate court recently rejected DOJ's damages-calculation approach of trebling the "gross loss" to the government and then deducting offsets. The court held that a defendant liable under the FCA must pay three times the amount of the government's "net loss," calculated by applying offsets before trebling. *U.S. v. Anchor Mortgage Corp.*

- The two recent civil actions against Novartis allege a pattern of kickbacks in the form of rebates, discounts and physician "incentive programs." Although at the time of this webinar Novartis had not yet filed an answer, it is noteworthy that discounts are protected in the safe harbor to the Anti-Kickback Statute.
- Panelists advised that although settlement may be the best resolution in some cases, companies should seriously consider being more aggressive in defending themselves (and prepare for such a posture at the outset of an investigation) given the government's increasingly excessive settlement demands as well as the potential costs associated with reputational harm and sweeping monitoring and reporting requirements.

DOJ & FDA Enforcement Developments

Jennifer Bragg | Washington, D.C.
John Bentivoglio | Washington, D.C.

In 2012 DOJ recovered nearly $6 billion in settlements with 15 pharmaceutical and device companies. Panelists reviewed notable developments in pharmaceutical and device enforcement and stressed the importance of rigorous internal controls.

- Ten of the 15 settlements involve a criminal component, including one felony, three misdemeanors, and one deferred prosecution agreement.
- The largest settlements of 2012 involved off-label promotion and were calculated based on gross sales of the relevant products rather than the severity of the alleged violation.
- One recent trend in enforcement actions is a new focus on "publication strategies" involving of Phase IV studies for non-indicated conditions. Prosecutors allege that companies have promoted such studies, including allegations of cherry-picking results, thereby avoiding Food and Drug Administration (FDA) approval requirements. Such allegations were made in the recent Forest, Abbott, and GlaxoSmithKline settlements.
- Another recent enforcement trend is increasing scrutiny of company interactions with payers. A review of recent settlements indicate that key risk areas include submissions to compendia and interactions with payers around coverage of new products. Look out for financial relationships that might raise Anti-Kickback Statute concerns or promotional activities that might violate FDA regulations.
- Deviations from current Good Manufacturing Practice (cGMP) can be another significant source of risk for companies. FDA has recently issued a sort of "super" warning letter requesting that some pharmaceutical and device companies retain third-party consultants to address cGMP issues. These "requests" often also ask companies to provide FDA with a copy of the third-party report and certification that the CEO has read and initiated recommended corrections.
- FDA civil enforcement actions were down in 2012 from 2011 levels and, despite talk of increased enforcement activity, FDA's enhanced efforts have largely been focused on the food and dietary supplement industries.

International Anti-Corruption Enforcement in the Health Care Sector: Recent Developments & Emerging Trends

Gary DiBianco | London
Bernd R. Mayer | Frankfurt and Munich

This panel provided a review of current trends and developments in the enforcement of international anti-bribery statutes and the challenges companies face in ensuring that their global operations remain compliant with all of the governing anti-corruption laws.

- International anti-bribery efforts continued to be a focus of international regulators, particularly given ongoing active cooperation between U.S. and non-U.S. law enforcement agencies. In addition to working with governments outside of the U.S., DOJ is providing cooperation credit to companies providing information about their competitors. When considering whether to self-report, companies should be aware of what the U.S. authorities may discover from sources over which they have no control.
- FCPA investigations and settlements often are clustered within specific geographic regions, industries and distributor networks. Prosecutors are focused on areas where there is a high level of perceived corruption.
- The conduct at issue in FCPA investigations often includes distributor relationships, consulting fees, speaker fees, key opinion leader agreements, travel, conferences, hospitality, charitable donations, third-party advisors and payments in connection with clinical trials, regulatory approvals, registrations and formulary inclusion. Companies are advised to have strong controls and to take corrective measures upon discovering problematic individual behaviors, policies or enforcement practices.
- In addition to standard requirements of an effective compliance program, the DOJ has imposed industry-specific "enhanced compliance obligations" in recent settlements. These obligations can include the adoption of jurisdiction-specific gift, hospitality and entertainment policies, periodic risk-based "anti-corruption audits" and enhanced diligence prior to entering new business relationships.
- A question arising in many countries is whether private health care practitioners are public officials for the purpose of anti-bribery statues. Germany's Grand Criminal Panel of the Federal Supreme Court recently held that the country's anti-bribery laws do not apply to private practitioners who treat patients insured through the public sick funds.

Deal Implications: Structuring, Negotiating and Consummating an Acquisition in the Face of Enforcement and Litigation Challenges

Stephan Hutter | Frankfurt
Jeremy D. London | Washington, D.C.
Paul T. Schnell | New York

This panel explored the risk of "purchasing" a compliance problem that began before acquisition. Skadden partners provided suggestions for how to allocate regulatory and compliance risk in a transaction.

- If a compliance problem arises at the target, government agencies will evaluate the purchaser's pre-acquisition diligence and post-acquisition efforts to investigate compliance practices, correct problems and self-report wrongdoing.

- Various contractual provisions—including representations and warranties, closing conditions, indemnification, contingent consideration and covenants—offer buyers some remedies. These contractual protections are necessary but, without effective pre-acquisition regulatory diligence, they generally are insufficient to protect against all risk of an acquired company's prior non-compliance.

- Thorough pre-acquisition regulatory due diligence is necessary to ensure that the buyer avoids entering an ill-advised deal. In addition, effective due diligence may provide safeguards against regulatory liability, identify valuation issues and enable the buyer to negotiate a purchase price that accounts for risk. However, the buyer must structure the diligence process in a way that is acceptable to the seller, which may be resistant to extensive diligence.

Under the FCPA a minority owner may face all of the legal consequences of a violation without actually having had the power to enforce compliance and remedy a problem. Buyers of substantial minority shares should consider seeking rights and remedies to advocate for greater corporate compliance and the ability to address issues on behalf of the minority investors or joint venture, should they arise.