Key Takeaways

Skadden

Third Annual Los Angeles Seminar for

Pharmaceutical, Biotechnology and Medical Device Companies

A Dialogue on Enforcement Actions, Securities Litigation, and Special Issues Facing Boards of Directors

Contacts

Brian J. McCarthy
213.687.5070
brian.mccarthy@skadden.com

John T. Bentivoglio
202.371.7560
john.bentivoglio@skadden.com

Jennifer Bragg
202.371.7980
jennifer.bragg@skadden.com

Gregory Luce
202.371.7310
greg.luce@skadden.com

Michael Loucks
617.573.4840
michael.loucks@skadden.com

Peter Morrison
213.687.5304
peter.morrison@skadden.com

Amy Park
650.470.4511
amy.park@skadden.com

Graham Robinson
617.573.4850
graham.robinson@skadden.com

Four Times Square
New York, NY 10036
212.735.3000

300 South Grand Avenue
Suite 3400
Los Angeles, California 90071
213.687.5000

On June 18, 2015, Skadden hosted its Third Annual Seminar for Pharmaceutical, Biotechnology and Medical Device Companies. The seminar focused on the current and developing challenges facing these companies and included panels comprised of Skadden partners and industry professionals.

Recent DOJ, OIG and FDA Enforcement Actions

The panel discussed trends in Department of Justice (DOJ), Office of the Inspector General (OIG) and Federal Drug Administration (FDA) settlements, including the relationship between criminal and civil enforcement actions, the size of companies subject to investigation, changes in government enforcement and settlement requirements, shifts in the FDA's enforcement focus, industry-wide compliance efforts and court challenges based on First Amendment protections, among other issues.

- Annual total settlement amounts from health care fraud enforcement actions against pharmaceutical and medical device manufacturers have declined steadily from a high of approximately $6 billion in 2012 to $1.21 billion in 2013, $444 million in 2014 and $86.4 million in the first four months of 2015.
- DOJ increasingly is looking to pursue both criminal and civil enforcement actions. DOJ officials recently announced that virtually all False Claims Act (FCA) complaints will be reviewed by both criminal and civil prosecutors (in contrast to the prior policy, which gave U.S. Attorney's Offices discretion on review procedures). In addition, DOJ and the SEC are sharing information on pharma/device sales and marketing cases for potential parallel efforts by SEC investigators, though the panelists were not aware of any recent settlements resulting from such enhanced DOJ-SEC cooperation.
- Numerous smaller companies have faced enforcement actions in 2014 and 2015. These investigations often have involved scrutiny of and/or charges against company executives, due in part to the fact that such individuals in smaller companies may be more closely tied to the underlying misconduct. Government officials continue to emphasize the importance of prosecuting individuals for the most serious types of misconduct (*e.g.*, cases involving harm to patients), both to hold such individuals accountable and to provide an effective deterrent to executives in other companies.
- Overall, core underlying violations continue to involve: (1) marketing and promotional practices, and (2) financial relationships with physicians and others in a position to purchase, prescribe or recommend a company's products.

  - Prior enforcement actions mostly centered around marketing and promotional violations, but settlements now also reflect DOJ's willingness to pursue manufacturing violations under the civil FCA.
- Increasingly, federal enforcement officials are willing to settle cases without requiring companies to enter into corporate integrity agreements (CIAs). This change largely reflects the OIG's limited resources for negotiating and monitoring CIAs, the narrower scope of recent investigations and settlements, and improved compliance programs in many life sciences companies.
- The FDA has shifted its enforcement focus toward cases involving serious public health and safety issues. There has been a notable increase in enforcement actions targeting food manufacturers, including criminal prosecutions of companies and individuals in cases involving the deaths of consumers. Importantly, these food cases — which are prosecuted under the same criminal provisions of the federal Food, Drug and Cosmetic Act as are pharma/device sales and marketing cases — are building a body of precedents that could prove influential in future prosecutions of pharmaceutical, biotechnology and medical device companies. Recent cases have demonstrated that companies that cooperate with government inquiries and take prompt and meaningful corrective actions can have a positive impact on prosecutorial decision-making.
- This year also saw free speech issues re-emerge following the Second Circuit's 2012 decision in *United States v. Caronia*. As one example, in the face of FDA's decision not to approve certain truthful, nonmisleading promotional messages relating to the beneficial reduction of triglycerides from the company's purified fish oil product, Amarin and several physicians challenged the agency's actions on First Amendment grounds. The FDA subsequently loosened its proposed restrictions on Amarin's promotional messages, but the company is continuing to pursue its First Amendment challenge. The panelists noted that DOJ prosecutors appear to be focusing more on false and misleading promotional messages and less on truthful but unapproved statements in response to these First Amendment developments, despite public assertions by DOJ officials that the *Caronia* decision and company-initiated First Amendment challenges have had little or no impact on their enforcement efforts.
- As companies adopt "bring your own device" policies for employees, the government has increasingly subpoenaed texts, emails and other data on employees' personal devices. The panel discussed early implementation of policies on personal devices that strike a balance between evidence preservation, cost efficiency and respect for employee privacy.
- Earlier cases generally did not admit statistical evidence to establish scienter, materiality or falsity under the FCA. Proof of damages, but not elements of liability, were commonly offered through extrapolated statistics. Recently, some courts are allowing statistical evidence to establish liability by suggesting that elements of FCA violations can be proven through statistical extrapolation to show patterns and practices.

Securities and M&A Litigation Update

Pharmaceutical, biotechnology and medical device companies represented 25 percent of total 2014 filings, with the number of filings overall increasing by a modest 2 percent, according to statistics published by Cornerstone Research. Last year saw a 111 percent increase in filings against biotechnology firms. The panelists discussed ways to attempt to reduce companies' securities litigation risk.

- Courts have found that when a company accurately and fully discloses a study's methodology and design, plaintiffs cannot state a claim for violation of the securities laws based solely on *criticisms* of the study's methodology and design, as opposed to allegations about the *disclosure* of the study's methodology and design. Thus, companies should consider providing careful, fulsome disclosure concerning a study's design and methodology, including, for example, information about participant numbers and/or whether a study is single- or double-blind.
- If a company must or elects to disclose information concerning a product's efficacy or safety, the company should ensure appropriate consideration is given to a full description of the product's efficacy characteristics and/or safety profile, including adverse effects.
  - At least one court has denied a motion to dismiss where allegations asserted that a company did not fully disclose certain adverse information, even where such information could be found publicly on the FDA's website.
  - Moreover, courts continue to apply the Supreme Court's ruling in *Matrixx Initiatives, Inc. v. Siracusano*, ruling that even if information concerning adverse events is statistically insignificant, such information may still be material to shareholders under the law and should be disclosed.

- Courts have looked closely at whether public statements concerning regulatory compliance are legally protected opinions by management or actionable representations of fact. In certain circumstances, courts may strike "throat-clearing" language attempting to hedge statements about regulatory compliance. For example, the statement that "we believe we are in compliance" may be read by some courts as "we are in compliance." According to a recent decision, simply affixing "we believe" language will not necessarily transform a statement into a protected opinion. This is not, however, a reason for companies to eschew such language when they believe they are offering an opinion.
- Courts have examined disclosure obligations concerning communications with the FDA. One New York district court recently found that companies did not have an obligation under the securities laws to disclose every interim FDA communication, because the court understood that interim communications with the FDA were, by definition, part of an ongoing, iterative process and that the disclosure of such interim back and forth could itself be misleading.
- Courts have recently found that statements about prospects for FDA approval and the anticipated time for a product's launch likely are inactionable opinions and/or predictions when such statements are forward-looking and couched in cautionary language.
- Courts have examined whether the announcement of a regulatory investigation can give rise to a federal securities lawsuit. The Ninth Circuit, following the Eleventh Circuit, found that such an announcement cannot be the basis of a securities action, as the announcement of a government investigation into a company, without more, cannot constitute a corrective disclosure under the federal securities laws. Thus, a stock price drop in reaction to the announcement of a government investigation cannot form the basis of a plaintiff's loss causation allegation.

The panel also discussed recent trends in merger litigation and developments. Merger litigation remains prevalent, with 93 percent of mergers and acquisitions valued over $100 million facing shareholder lawsuits in 2014.

Special Issues Facing Boards of Directors

The panelists discussed managing a buyer's due diligence review of sensitive information, the role of the buyer's board in due diligence and cases of board liability in approving the sale of a company.

- Reliance on nondisclosure agreements to protect sensitive information can present certain risks, including the difficulty of proving a breach of such an agreement. Tools to manage sensitive information include delaying its disclosure while supplying only broad indications as to its content; limiting the review to third parties, small groups or in-person physical review; and extending nondisclosure agreement time periods.
- As part of the exercise of its duty of care, a buyer's board should have a record that it participated in structuring the due diligence review and was informed of important findings. Minutes should reflect that boards engaged with due diligence to a degree correlated to the significance of the transaction and the risks involved.
- The panel recommended a buyer's board's involvement early in the transaction process to identify key areas of potential risk regarding an acquisition and to assist in structuring the due diligence process. Boards should be involved prior to approving the transaction, in order to follow up on previously identified and new areas of risk, as well as on any limitations or restrictions on due diligence.
- Finally, the panel covered recent cases addressing liability of target directors in approving a sale of a company. With some exceptions, independent directors approving a sale of a company generally are shielded from personal liability by Section 102(b)(7) of the Delaware General Corporate Law. The principal exception to this protection arises if a director acts in "bad faith," which historically has been interpreted in a way that is very protective of well-intentioned independent directors. A number of recent cases addressing 102(b)(7) have raised questions about whether this protection is shrinking. The panel discussed these recent cases, including the Delaware Supreme Court's recent decision in *In re Cornerstone Therapeutics*, and concluded that on the whole, independent directors should feel that they remain strongly protected by Section 102(b)(7).