PUBLICATION

Silence is Not Always Golden: Recent Pharmaceutical Company Settlement with SEC Illustrates Various Risks Related to Disclosure Obligations of Reporting Companies

December 02, 2019

Overview

Publicly-traded companies that operate in highly regulated industries, such as in the health care sphere, often face difficult decisions about what information (if any) they should disclose to investors and others, when to disclose that information, and how to disclose it. "The life sciences industry encounters heightened securities fraud liability for several reasons – it is heavily regulated, highly profitable, and one in which a small fraction of new products will ultimately get approved for sale and marketing."[1] In general, but subject to important exceptions, our securities laws in the United States do *not* require continuous disclosure of information. But when disclosures are made, they must be truthful and accurate. If disclosures have already been made, then companies face important related considerations – whether and when to provide *corrective information* about prior disclosures that, even though they were accurate when made, may have become inaccurate or misleading due to new developments.[2] The so-called *duty to update* places "a proactive responsibility [on listed companies] to inform the marketplace when events evolve ... to render misleading some prior statement upon which the market is still relying."[3] A corollary doctrine is the *duty to correct* a prior disclosure; it is only imposed if a prior disclosure was misleading or false when it was made.

Mylan's recent settlement with the Securities Exchange Commission (SEC or Commission) serves as a reminder about what constitute the best practices and other strategical considerations that listed companies need to consider when facing a disclosure decision. In the SEC's public release entitled "Mylan to Pay $30 Million for Disclosure and Accounting Failures Relating to EpiPen," LITIG. REL. No. 24621 (Sept. 27, 2019), the Commission summarized the terms and basis for its settlement with Mylan N.V., the world's second-largest generic and specialty pharmaceuticals company, to resolve the allegations made in its simultaneously filed complaint. See *Securities and Exchange Commission v. Mylan N.V.,* No. 19-civ-2904 (D.D.C.). Critically, the SEC explained that the underlying basis for pursuing Mylan for securities violations involved its failure to timely disclose material information and related accounting system failures:

As alleged in the complaint, public companies facing possible material losses from a lawsuit or government investigation must (1) disclose the loss contingency if a loss is reasonably possible; and (2) record an accrual for the estimated loss if the loss is probable and reasonably estimable. Mylan, however, failed to disclose or accrue for the loss relating to the DOJ investigation before October 2016, when it announced a $465 million settlement with DOJ. As a result, Mylan's public filings were false and misleading.

Further, as alleged in the complaint, Mylan's 2014 and 2015 risk factor disclosures that a governmental authority may take a contrary position on Mylan's Medicaid submissions, when CMS had already informed Mylan that EpiPen was misclassified, were misleading.[4]

In Part One of this series of Client Alerts, we begin by examining some of the major disclosure duties imposed by the federal securities laws before offering suggestions about how not to get cross-wise with the Commission and others. It is worth noting that the Commission's enforcement action against Mylan was *just one* of the litigation risks that it faced, as Mylan was also a named defendant in three other major cases:

1. a federal securities class action suit that generally alleged the company was involved in two categories of wrongdoing: Medicaid misclassification of its branded drug EpiPen Auto-Injector ("EpiPen") *and* antitrust violations. *See* Amended Class Action Complaint, Dkt. No. 39, filed in *In Re Mylan N.V. Securities Litigation*, No. 1:16-cv-07926-JPO (S.D.N.Y.);

2. *qui tam* actions that generally alleged it had misclassified EpiPen as a "non-innovator multiple source" drug (rather than a "single source" drug) for purposes of Medicaid's Drug Rebate Program and, as a result, had underpaid rebates owed under the Program for EpiPen.[5] *See* Press Release, U.S. Attorney's Office for the District of Massachusetts, "Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability" (Aug. 17, 2019) and the related Settlement Agreement;[6] and

3. a Consolidated Class Action Complaint that asserted federal and state antitrust claims, federal RICO Act violations, state consumer protection law violations, and unjust enrichment claims, and generally alleged that Mylan and others had monopolized the EpiPen market and obtained its profitable revenues by executing an illegal scheme that was carried out through several different avenues. See *In re: EpiPen (Epinephrine Injection, USP) Marketing*, MDL No: 2785 Sales Practices and Antitrust Litigation Case No. 17-md-2785-DDC-TJJ (D. Kan.).

To Speak, or Not to Speak, is the Question

"Our securities laws regulate publicly-traded entities by imposing disclosure duties and placing restrictions on fraud, manipulation, and insider trading."[7] Violations can lead to parallel administrative, civil, and criminal proceedings (along with significant fines, penalties, and restitution orders). In § 21(a) of The Securities Exchange Act of 1934 (Exchange Act), Congress gave considerable discretion to the Commission to investigate federal securities law violations.[8] "The SEC's primary enforcement actions include injunctive actions, actions for civil penalties, cease-and-desist orders, stop order proceedings, administrative proceedings against securities professionals, administrative proceedings pursuant to Section 15(c)(4) of the . . . Exchange Act, and administrative proceedings against professionals pursuant to Rule 102(e) of the SEC's Rules of Practice."[9] This part of the alert focuses on two major statutes that the Commission enforces which are relevant to disclosure considerations – The Securities Act of 1933 (Securities Act) and The Exchange Act. The Commission has promulgated numerous implementing regulations under these laws that are designed to protect the investing public and make financial markets more transparent. A brief discussion of these key laws is included for reference below.

The Securities Act

The Securities Act regulates the domestic securities markets in an *ex ante* fashion. "The Securities Act, [o]ften referred to as the 'truth in securities' law, has two basic objectives, to 'require that investors receive financial and other significant information concerning securities being offered for public sale' and to 'prohibit deceit, misrepresentations, and other fraud in the sale of securities.'"[10] "A primary means of accomplishing these goals is the disclosure of important financial information through the registration of securities. This information enables investors, not the government, to make informed judgments about whether to purchase a company's securities."[11] The Securities Act regulates initial public offerings of securities and requires most listed companies to follow proscribed registration procedures that require, among other things, specified information be included in a prospectus.[12]

The Exchange Act

Under Exchange Act §§13(a) and 15(d), issuers of registered securities must provide specific information in the format required by SEC rules or regulations, in periodic reports, including annual and quarterly reports. The

Seventh Circuit summarized the major disclosure obligations of issuers under federal securities law in *Gallagher v. Abbott Laboratories*, 269 F.3d 806 (7th Cir. 2001), as follows:

We do not have a system of *continuous disclosure*. Instead firms are entitled to keep silent ... unless positive law creates a duty to disclose.... The 1933 Act requires firms to reveal information only when they issue securities, and the duty is owed only to persons who buy from the issuer or an underwriter distributing on its behalf; every other transaction is exempt under §4, 15 U.S.C. §77d. ... Section 13 of the ... Exchange Act ... adds that the SEC may require issuers to file annual and other periodic reports – with the emphasis on *periodic* rather than continuous. . . (emphasis added).[13]

As initially noted, this general rule allowing a listed company to remain silent until required to disclose information is subject to various exceptions. Most securities fraud actions are based on alleged violations of Section 10(b) of the Exchange Act and its implementing rule, 10b-5, which have a much broader reach than their counterparts under the Securities Act (that must involve fraudulent conduct related to a *public offering*).[14]

What Constitutes "Material Information" for Disclosure Purposes?

"Congress did not define the [key] term 'materiality' in either the Securities Act or the Exchange Act."[15] This has resulted in scholarly commentary and regulatory interpretation about what constitutes material information to be disclosed – i.e., should it be analyzed using a *quantitative* approach; a *qualitative* one, or a *hybrid*?[16] There has also been debate about *what information* a publicly-traded company must disclose (and *when* and *how* to make such disclosures). The Commission rejects using a quantitative or qualitative approach in favor of what it calls "robust" principles-based disclosures. As an SEC official recently explained:

[O]ur disclosure requirements are intended to provide investors with the material information they need about companies and their securities offerings to make informed investment and voting decisions. Robust disclosure decreases information asymmetries and is the foundation of reliable price discovery. When investors have confidence that they are receiving full and transparent disclosure, markets operate more efficiently and the cost of capital is reduced. …

"Our disclosure regime emphasizes materiality. Information is material if there is a substantial likelihood that a reasonable investor would consider it important in deciding how to vote or make an investment decision. Principles-based disclosure requirements articulate an objective and look to management to exercise judgment in satisfying that objective by providing appropriate disclosure when necessary."[17]

In general, the amount of information required by the Commission to be disclosed has *increased* even as the timeframe to do so has *decreased*.[18] We believe it is ordinarily a best practice to err in favor of more liberal disclosures when considering the risks involved (which is always a facts-and-circumstances decision). Some key SEC Staff Accounting Bulletins to consider reviewing when making this determination are SAB No. 99 – Materiality; SAB No. 100 – Restructuring and Impairment Charges; and SAB No. 101 – Revenue Recognition.

The judicial standard for determining materiality is that "[w]hether a fact is material 'depends on the significance the reasonable investor would place on the withheld or misrepresented information.'"[19] A lot of information simply is not material for disclosure purposes. For example, courts do not protect "soft" information upon which no reasonable investor could rely (such as when companies use "puffing" to market their products),[20] and since the securities laws do not protect foolish investments, courts will examine the total mix of information in the marketplace to determine if a company's failure to disclose is actionable.[21] "In analyzing Rule 10b-5 causation issues, courts often state that investors may not simply close their eyes to obvious risks, but must exercise due diligence in protecting themselves."[22]

In the next related Client Alert, we examine the key regulations that mandate periodic and episodic disclosures, the events that led to the SEC's enforcement action against Mylan on the heels of the company's settlement of qui tam suits with the DOJ, and then offer some practical advice for reporting companies about how to assess and respond to the various risks presented under different scenarios.

[1] Michael E. Clark, *Securities Law Issues and Disclosure Considerations for Life Sciences Companies*, at 12-3, PHARMACEUTICAL AND MEDICAL DEVICE LAW: REGULATION OF RESEARCH, DEVELOPMENT, AND MARKETING, (Bloomberg BNA/ABA Health Law Section, 2d Ed. 2015) (Michael E. Clark, Ed.). A substantial part of this discussion is derived in whole or part from this chapter of the treatise. More detailed analysis about these and related issues are set out in this lengthy chapter of the treatise.

[2] See Clark, *Securities Law Issues and Disclosure Considerations for Life Science Companies*, at 12-9.

[3] Donald C. Langevoort, *Organized Illusions: A Behavioral Theory of Why Corporations Mislead Stock Market Investors (and Cause Other Social Harms),* 146 U. PA. L. REV. 101, 163 (1997) (internal notes omitted).

[4] "Mylan to Pay $30 Million for Disclosure and Accounting Failures Relating to EpiPen," Litig. Rel. No. 24621.

[5] On July 29, 2016, Sanofi-Aventis US LLC filed a *qui tam* action in the District of Massachusetts captioned *United States, et al. ex rel. Sanofi-Aventis US LLC v. Mylan Inc., et al*., No. 16cvl 1572-ADB, under the False Claims Act, 31 U.S.C. § 3730(b), and an amended *qui tam* complaint on August 4, 2016. On December 8, 2016, Ven-A-Care of the Florida Keys, Inc. filed a *qui tam* action in the Southern District of New York captioned *United States, et al. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Mylan Inc., et al.,* No. 16-CV-9484 (JGK), and an amended *qui tam* complaint on January 3, 2017. On January 19, 2017, Ven-A-Care's *qui tam* action was transferred to the District of Massachusetts and assigned Case No. 17-10140-ADB.

[6] As noted in this press release issued by the U.S. Attorney's Office for the District of Massachusetts, Mylan Inc. and Mylan Specialty L.R, both wholly owned subsidiaries of Mylan N.V., agreed to pay $465 million to resolve allegations that they violated the False Claims Act by knowingly misclassifying EpiPen, a branded epinephrine auto-injector drug, as a generic drug to avoid paying larger rebates owed to Medicaid.

[7] Michael E. Clark, *The Growing Importance of Securities Regulation for Publicly Traded Entities in the Post-Sarbanes-Oxley Marketplace,* 2006 HEALTH LAW AND COMPLIANCE UPDATE §5.01 (internal notes omitted).

[8] "Section 21(a) further authorizes the Commission to investigate any facts, conditions, practices, or matters which it may deem necessary or proper to aid in the enforcement of such provisions, in the prescribing of rules and regulations under the . . . Exchange Act, or in securing information to serve as a basis for recommending further legislation." Ralph C. Ferrara & Philip S. Khinda, *Overview of an SEC Proceeding,* 30TH ANNUAL INSTITUTE ON SECURITIES REGULATION, 1085 PLI/CORP. 597, 610 (1998) (emphasis added). Sections 8(e) and 20(a) of the Securities Act are companion provisions to Section 21(a) of the Exchange Act. *Id.*

[9] Ferrara & Khinda, 1085 PLI/CORP. at 636.

[10] Clark, *Securities Law Issues and Disclosure Considerations for Life Science Companies*, at 12-19 n.83 (citing *The Investor's Advocate: How the SEC Protects Investors, Maintains Market Integrity, and Facilitates Capital Formation;*) *available at* http:www.sec.gov/about/whatwedo.shtml).

[11] *Id.* (at 12-9 n.84).

[12] Clark, *Securities Law Issues and Disclosure Considerations for Life Science Companies*, at 12-20.

[13] Gallagher*,* 269 F.3d at 808–10 (internal citations omitted). The *Gallagher* court's opinion also addressed the plaintiffs' arguments: "[P]laintiffs insist that Abbott had a "duty to correct" the 10-K report. Yet a statement may be "corrected" only if it was *in*correct when made. . . [.] In order to maintain the difference between periodic-disclosure and continuous-disclosure systems, it is essential to draw a sharp line between duties to correct and duties to update. . . ."). *Id.*

[14] Section 10(b) of the Exchange Act, codified as amended at 15 U.S.C. §78j(b), provides in relevant part:

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange – . . . [t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

In turn, Rule 10b-5, codified as amended at 17 C.F.R. §240.10b-5, provides:

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,

(a) To employ any device, scheme, or artifice to defraud,

(b) *To make any untrue statement* of a ***material fact*** *or* to *omit to state a material fact necessary … to make the statements made, in the light of the circumstances under which they were made, not misleading*, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

(Emphasis added)

[15] Clark, *Securities Law Issues and Disclosure Considerations for Life Science Companies*, at 12-25.

[16] *See id.*

[17] Speech by William Hinman, Director, Division of Corporation Finance, SEC, "Applying a Principles-Based Approach to Disclosing Complex, Uncertain and Evolving Risks: Remarks at the 18th Annual Institute on Securities Regulation in Europe," London, England (March 15, 2019) (internal notes omitted); *available at* https://www.sec.gov/news/speech/hinman-applying-principles-based-approach-disclosure-031519.

[18] *See generally,* Seth Aronson et al., *Understanding the Securities Laws 2003: Liability for Exchange Act Violations,* UNDERSTANDING THE SECURITIES LAWS, 1385 PLI/CORP. 834, 836 (2003) ("With the Sarbanes-Oxley Act of 2002, companies . . . [must] make certain real-time disclosures. . . . Issuers . . . [must] 'disclose . . . on a rapid and current basis such additional information concerning material changes in the financial condition or operations of the issuer, in plain English . . . as the Commission determines, by rule. . . .' 15 U.S.C. §78m(I). . . . [A] failure to do so can give rise to civil liability. . . . These disclosures include: (1) A change in control . . . ; (2) The company's acquisition or disposition of a significant amount of assets; (3) The company's bankruptcy or receivership; (4) A change in the company's certifying accountant; (5) The resignation of a company director; and (6) A change in the company's fiscal year. 15 U.S.C. §78m(I).").

See also SEC Release Nos. 33-8400; 34-49424; File No. S7-22-02, *Final Rule*: *Additional Form 8-K Disclosure Requirements and Acceleration of Filing Date* (Aug. 23, 2004), explaining why and how the Commission changed Form 8-K's reporting requirements:

Under the previous Form 8-K regime, companies were required to report very few significant corporate events. The limited number of Form 8-K disclosure items permitted a public company to delay disclosure of many significant events until the due date for its next periodic report . . . . The revisions that we adopt today will benefit markets by increasing the number of unquestionably or presumptively material events that must be disclosed currently. They will also provide investors with better and more timely disclosure of important corporate events.

On July 29, 2002, Congress enacted the Sarbanes-Oxley Act of 2002. Section 409 of this Act requires public companies to disclose "on a rapid and current basis" material information regarding changes in a company's financial condition or operations as we, by rule, determine to be necessary or useful for the protection of investors and in the public interest . . . .

[19] Alan J. Berkeley, *Materiality, Informal Disclosure, Soft Information, and Forward-Looking Statements Under Securities Laws* 247, 249 (ALI-ABA SH001, 2002), citing *Basic Inc. v. Levinson*, 485 U.S. 224, 240 (1988).

[20] *See, e.g.*, *Indiana State District Council of Laborers & Hod Carriers Pension & Welfare Fund v. Omnicare, Inc.*, 583 F.3d 935 (6 Cir. 2009), where the court largely affirmed the dismissal of a class action complaint. As the *Omnicare* court explained, disclosure was not required since the information was soft; moreover, the company had no duty to disclose illegal activities (even though it had claimed to be in legal compliance). *Id*. at 945.

[21] See C. Edward Fletcher, *Sophisticated Investors under the Federal Securities Laws,* 1988 DUKE L.J. 1081, 1090 (1988).

[22] Fletcher, *Sophisticated Investors under the Federal Securities Laws,* 1988 DUKE L.J. at 1087-88 (internal notes omitted).