Securities
Regulation Daily

Wolters Kluwer

December 12, 2019

Silence Is Not Always Golden:

Recent Pharmaceutical Company Settlement With SEC Illustrates Various Risks Related To Disclosure Obligations of Reporting Companies

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Overview

Publicly traded companies that operate in highly regulated industries, such as in the healthcare 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 for listed companies 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.

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> 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 this piece, we examine some of the major disclosure duties imposed by the federal securities laws and offer 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 the company faced since 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] We begin by looking at two major statutes that the Commission enforces that are important for 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 each Act is included for reference below.

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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 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 approach in favor of "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

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> 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 that, ordinarily, it is a best practice to err in favor of more liberal disclosures after considering the risks involved (but acknowledge this is always a facts-and-circumstances decision and may be counterproductive). 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]

Key SEC Regulations and Rules that Mandate Periodic and Episodic Disclosures

Among the SEC regulations and rules that mandate periodic and episodic disclosures are the following:

- Regulation S-K (pertaining to registration statements)—including Item 10b (policy on projections), Item 103 (pertaining to legal proceedings), Item 303 (MD&A), Item 401(f) (concerning directors, executive officers, promoters, and control persons), Item 404(a) (concerning self-dealing and related transactions), and Item 503(c) (involving risk factors);
- Regulation S-X (proscribing the form, content, and requirements for financial statements required to be filed as a part of registration statements under the Securities Act, and the form, content, and requirements for financial statements required to be filed as a part of annual or other reports under the Exchange Act)—including Articles 3 (general instructions for financial statements) and 10 (interim financial statements) and various periodic forms (8-K, 10-Q, 10-K); and
- Regulation FD (requiring simultaneous public disclosure of material information when the information has been provided to a specified list of recipients).

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Regulation S-K

"Item 103 of Regulation S-K[23] requires disclosing 'any material pending legal proceedings" against a corporation, including "the name of the *court or agency* in which the proceedings are pending, the date instituted, the principal parties thereto, a description of the factual basis alleged to underlie the proceeding and the relief sought.' "[24] This obligation also encompasses "similar information as to any such proceedings known to be contemplated by governmental authorities."[25]

Regulation S-X

Item 303 of Regulation S-X, "Management's Discussion and Analysis" (MD&A),[26] is another important disclosure requirement, even though plaintiffs have not succeeded in having defendants found liable for false or misleading disclosures that violate its requirements since no private cause of action is recognized such violations, as explained in *In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 403 (6th Cir. 1997).[27] On the other hand, the *Commission* has successfully brought enforcement actions for violating this reporting obligation (since it has the authority to do so). *See, e.g. In re Andrx Corp.*, No. 3-11107, 2003 SEC LEXIS 1082 (S.E.C. May 6, 2003).[28] Article 3 of Regulation S-X sets out the accounting rules about the form and content of financial statements required for disclosure documents. Its general instructions specify the balance sheets and statements of income and cash flows that must be included in these disclosure documents. Article 10 of Regulation S-X requires issuers to file interim financial statements to help investor obtain accurate and reasonably current information. Issuers must include enough information to prevent their disclosures from being misleading—which implicitly seems to impose on issuers a duty to update under some circumstances.

Regulation FD (Fair Disclosure)

Under Regulation FD, codified as amended at 17 C.F.R. §243.101, if an issuer (or someone acting on its behalf) discloses material nonpublic information about it or its securities, then the issuer must publicly and simultaneously disclose information that was intentionally disclosed *or* promptly disclose information that was unintentionally disclosed.[29]

Events Leading up to the SEC Enforcement Action Against Mylan (Hell hath no Fury Like a Regulator Scorned)

The Government and the public have become increasingly concerned about the mounting costs of prescription drugs. *See, e.g.*, Samantha DiGrande, "Pharma Companies Raise Prices on More than 250 Drugs in 2019," The Center for Biosimilars (Jan. 3, 2019) (noting, *inter alia*, that "[a]fter several pharmaceutical companies agreed to halt drug price increases in 2018 after receiving pressure from the Trump administration, the industry has kicked off 2019 with price increases on more than 250 prescription drugs."). This concern is heightened when the product in question, such as Mylan's EpiPen, is a life-saving drug, when demand for the product is inelastic, and when competition for the product is minimal or non-existent. As noted, Mylan drew that unwanted attention. Some key alleged events that caused this negative attention are set out in a *Memorandum Opinion and Order* issued in the Consolidated Class Action litigation, *In re: EpiPen (Epinephrine Injection, USP) Marketing*:

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> In 2007, Mylan acquired the right to market and distribute the EpiPen. Pfizer is the exclusive supplier of EpiPens to Mylan. Pfizer provides Mylan with 100% of its EpiPen supply through two of its wholly owned subsidiaries ... who manufacture the epinephrine and hold the EpiPen patents. ... Since 2009, Mylan's market share consistently has exceeded 90%, and, in 2012, its share was almost 100%. During the same time—and while the cost of the EpiPen's dose of epinep]hrine has remained about $1—Mylan has increased the EpiPen's price by more than 600%. In 2007, Mylan priced the EpiPen at $100. By 2016, Mylan was charging more than $600.[30]

On October 3, 2016, CNBC reported that the Congressional House Oversight and Government Reform Committee, sent a letter to Mylan's CEO demanding that Mylan produce documents about its profits from EpiPen.[31] This letter came after the CEO testified in late September 2016 in a hearing about EpiPen's price increases. She was questioned about why its price had increased over 500% in seven years and defended the increases by saying that Mylan had expanded EpiPen's availability to consumers.[32]

Armed with the benefit of 20-20 hindsight, clearly Mylan should have been more liberal in making its disclosures. We believe that companies should look beyond their statutory and caselaw reporting obligations when considering disclosure obligations. They should also consider the actual or likely negative publicity from not disclosing, or providing limited disclosure of, such information to properly assess the risks and think about, among other things, how the Commission would respond to such a course of conduct *and* how contingency fee lawyers would characterize it in class action strike suits. Those assessments must be weighed against making a *premature disclosure* of an investigation, which can needlessly harm the company.[33]

Practical Considerations

Various circumstances can develop that also will require close attention to a company's disclosure obligations and the timing of a disclosure, such as when, as in Mylan's case, a partial unsealing of a False Claims Act case is made to a company or a subsidiary that is determined to be material; when a company is an announced target of a government investigation; when a company receives a *non-routine* government subpoena; when a company's senior officer comes under investigation; or when a company's regular auditors ask about an ongoing investigation.

Disclosure Considerations for Dealing with a Partially Unsealed Qui Tam Suit

Federal False Claims Act cases filed by whistleblowers make disclosure obligations a bit tricky since these lawsuits are required to be filed under seal.[34] The Act authorizes private plaintiffs ("called relators") to file *qui tam* suits in the name of the Government to recover damages. In addition to filing their lawsuits under seal, relators must also provide a copy of their "disclosure statements" about the supporting evidence to the U.S. Department of Justice so that it can investigate and evaluate the allegations before deciding whether to intervene or let the plaintiff pursue the action. Unbeknownst to the defendants, cases may remain under seal for years while the Government investigates the allegations. Often, the first time when a defendant named in a *qui tam* suit will have reason to suspect that there is a sealed lawsuit is when the Government issues a civil investigative demand (CID) for evidence of possible statutory violations. When that happens, a company may then decide to ask

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the Government to get court authorization to "partially unseal" the complaint so that it can evaluate the allegations and try to persuade the Government not to intervene, or else negotiate a settlement. Learning about a sealed *qui tam* suit presents a practical issue as the company cannot disclose information in a sealed lawsuit. Consequently, as soon as a company decides to make a disclosure after evaluating the *qui tam*, it should seek permission to have the case unsealed so it can meet its disclosure obligations.

Disclosure Considerations for a Company that is a Target of an Investigation

DOJ Investigations

The U.S. Department of Justice uses three distinct categories for describing individuals or entities in an investigation: (1) "targets," (2) "subjects" or (3) "witnesses." These can be fluid concepts, as a person who starts off as a witness can become a target based on evidence obtained in an investigation.

> It is the policy of the Department of Justice to advise a grand jury witness of his or her rights if such witness is a "target" or "subject" of a grand jury investigation. ...
>
> A "target" is a person as to whom the prosecutor or the grand jury has substantial evidence linking him or her to the commission of a crime and who, in the judgment of the prosecutor, is a putative defendant. An officer or employee of an organization which is a target is not automatically considered a target even if such officer's or employee's conduct contributed to the commission of the crime by the target organization. The same lack of automatic target status holds true for organizations which employ, or employed, an officer or employee who is a target.
>
> A "subject" of an investigation is a person whose conduct is within the scope of the grand jury's investigation.[35]

SEC Investigations

SEC Investigations differ from DOJ investigations. "Keeping with the fact-finding nature of the investigation, the SEC staff does *not* identify formal targets (in direct contrast to Department of Justice Procedure, which frequently involves the issuance of "target letters") either in the formal order of investigation, the subpoena, or orally as part of discussions with counsel."[36] The SEC's investigative process moves from an informal inquiry (called a "matter under inquiry") to a formal inquiry when senior SEC staff members approve the issuance of a formal order of investigation, to the so-called "Wells Process" during which the SEC invites parties to submit evidence or defenses to counter its theories of liability, to either a settlement that involves the entry of a consent decree and the filing of a complaint, or the institution of charges in either an administrative action or a civil lawsuit in federal court.[37]

A company that receives a *target letter* should immediately disclose that information. A target letter means not only does the DOJ *intend to indict* the company, but also that it *believes it has substantial evidence to link it* to the commission of a crime. The decision is more difficult, however, if a company has been informed that it is a *subject* of an investigation, since that means that the DOJ has *not yet*

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developed (nor may it ever develop) *enough evidence* to bring charges. While assessing whether to disclose such information requires a careful facts-and-circumstances analysis, we believe the best practice likely may be to err on the side of caution and disclose the investigation since not only is it more common for companies to be investigated, but not disclosing the investigation in a timely fashion may upset the SEC or DOJ and may haunt a company if charges get filed and class action counsel allege that the company's failure to disclose constitutes another fact in a chain of deception constituting a securities fraud scheme.

What about a company's obligation to disclose a Wells Notice? A company is not obligated to make a disclosure simply because it received such a notice. The SEC may decide not to pursue charges, depending on the evidence and responses provided by the recipient. There is also some supporting caselaw that the simple receipt of a Wells Notice does not trigger a disclosure obligation.

> On June 12, 2012, in the first case to expressly rule on this question, Judge Paul Crotty of the Southern District of New York found that there is no requirement to disclose receipt of a Wells Notice. The case, *Richman v. Goldman Sachs Group, Inc.*, involved a claim by class action plaintiffs that Goldman Sachs committed securities fraud by, among other things, failing to disclose receipt of a Wells Notice issued by the SEC staff in connection with an investigation about a synthetic collateralized debt obligation (CDO) transaction. Analyzing Regulation S-K Item 103, FINRA and NASD rules, as well as general securities fraud principles, Judge Crotty found that Goldman Sachs had no duty to disclose the Wells Notice. It should be noted that Goldman Sachs had disclosed generally that it had received requests from various government agencies and others for information related to CDOs and other subprime mortgage products—although Judge Crotty referred to this, his opinion does not appear to have turned on this point.[38]

See also, e.g., In re Lions Gate Entertainment Corp. Sec. Litig., 165 F.Supp.3d 1, 12-13 (S.D.N.Y. 2016) (citing *Richman*).[39] Nevertheless, it may be in a listed company's best interest to report the receipt of a Wells notice depending on if, after assessing the facts-and-circumstances, it determines the chances of convincing the Commission not to pursue an action appear to be low—*along with* considering how likely it is that not making the disclosure will harm its ability to negotiate a more favorable settlement.

Disclosure Considerations When a Company Receives a Non-Routine Government Subpoena

As noted above in describing how a Civil Investigative Demand often is the first sign of a Government *qui tam* investigation, some types of Government subpoenas likely signal major problems for a company. The receipt of a non-routine subpoena from the Government often triggers a "reactive" internal investigation aimed at determining the answers to many important questions, including:

- Does a major problem exist?
- How widespread is it?
- What caused it?
- Who knows about it?
- Are high-ranking company officials involved?

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- Should anyone be suspended or terminated?
- For how long has it gone on?
- Does it involve a compliance failure?
- What is the likely financial impact on the company?

Outside counsel who are experienced in overseeing a reactive internal investigation may decide to quickly engage Government officials in a dialogue to explain that the company wants to fully cooperate; needs to determine answers to some questions; wants to avoid interfering with the Government's investigation; wants to discuss narrowing the production of documents to what the Government really needs; and, seeks an agreement for a "rolling production" of documents. As compared with the execution of a search warrant (which often receives negative public attention), often the receipt of a non-routine subpoena is not public knowledge, so a listed company must quickly evaluate whether the scope of information sought likely signals there may be material information that should be disclosed. To make that determination, some reasonable time is needed for outside counsel to get answers to questions like those set out above, so that it can advise the company whether it may have an immediate disclosure obligation or not. Moreover, outside counsel can likely determine from discussions with Government officials their theories of potential liability; whether they believe that it is likely to result in some sanctions being imposed upon the company and/or high-ranking officials; and the likely timeframe before any final determination will be made.

Disclosure Considerations When a Company's Senior Officer Comes Under Investigation

Similar issues arise when a company's senior officer faces a Government investigation. In addition to the questions above, some other questions to be answered for assessing the company's disclosure obligations are:

- How important is he or she to the company's operations and success?
- How involved was he or she in the matters under investigation?
- Has he or she been identified as a target or a subject of the investigation?
- Does he or she need to be removed from current positions, temporarily or permanently?
- Will removing him or her result in immediate or adverse publicity?

There are other practical considerations associated with a senior officer coming under Government investigation, such as his or her right to have independent counsel, to have fees advanced upon signing a written undertaking pursuant to an indemnification agreement, and the company's obligation to forecast, report, and properly account for such legal costs in periodic or other required public filings. For these reasons, the company may determine that it makes sense to disclose such information.

Disclosure Considerations When a Company's Regular Auditors Ask About an Ongoing Investigation

"[A]ll public companies registered with the SEC ... [must] have their financial statements audited by an independent accountant. Such statements disclose a company's financial position, stockholders' equity, results of operations, and cash flows. Management is responsible for the

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preparation and content of … [the] financial statements, and the external auditor is responsible for auditing … [them] in accordance with Generally Accepted Auditing Standards."[40] The SEC also instructs national securities exchanges and associations not to list any issuer's security if it is not compliant with standards as to the issuer's audit committee—which relate to the audit committee's independence and responsibility for selecting an independent accountant and any outside auditors or advisors.[41]

"The auditor's goal is to provide an independent report on whether the company's financial statements present fairly the financial position of the company in conformance with GAAP, including disclosures and accruals for contingent liabilities. Statement of Auditing Standards ("SAS") No. 1238 provides the guidelines the auditor must follow in gathering such evidence from the client's attorneys."[42] Among other things, outside auditors must evaluate whether the supporting documentation for the public company's financial statements adequately reflect possible litigation losses and, if so, whether they provide realistic estimates:

> Financial accounting standard ASC 450-20 requires companies' financial statements to disclose information about possible litigation losses. If a company will "probab[ly]" suffer a loss and can "reasonably estimate[]" the loss amount, the financial statements must disclose the loss as a "charge to income." The financial statements also must disclose a potential litigation loss that is a "reasonable possibility," though not necessarily probable. In such disclosures, the company's financials must include "[a]n estimate of the possible loss or range of loss or a statement that such an estimate cannot be made."[43]

In enacting the 2002 Sarbanes-Oxley reform legislation, Congress wanted to make outside auditors more independent and thereby less susceptible to having client pressures impact their work.[44] Since an outside auditor serves as a "public watchdog," the auditor's interests will not necessarily align with the companies being audited. This creates difficulties for companies and their counsel when an auditor seeks privileged documents or asks questions for which the answers may waive subject matter privilege. By disclosing privileged material to an outside auditor, the company risks that an adversary, such as a government investigator or private plaintiff's counsel, will claim that its privileges were waived. Courts are split on this question, so knowing the controlling authority in the jurisdiction where the investigation is taking place, where the auditor is working, and where the company's operations extend is very important.[45] In such a circumstance, the company needs to find a way to mollify the auditor to avoid a negative result in the audit[46] while also avoiding or at least minimizing the privilege waiver concerns.

The same practical considerations previously discussed about carefully evaluating the facts-and-circumstances involved before making such a decision also apply. A best practice in this circumstance is to convey these concerns to the auditor to determine if the auditor absolutely needs the information to complete the audit or not.[47] If so, then the company should try to convince the auditor to obtain the requested information through means that are not as risky for waiving privileges. Here are some good suggestions that have been offered by others:

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- Disclosures to the auditors should be oral, not written.
- Do not interview memoranda or the written investigative report.
- Provide facts to answer the auditors' questions.
- Discuss the auditors' confidentiality obligations.
- Ensure there is a confidentiality agreement in place covering any information provided to the auditors as being confidential, not to be disclosed to others, and is subject to the work-product protection.
- Document the legal basis for the work-product protection.
- The agreement with the auditors should provide that in-house or outside counsel must be allowed to review any auditor work papers that may contain privileged material being produced if the auditor is subpoenaed.[48]

Conclusion

Publicly traded companies accept important disclosure obligations to the investing public in return for being able to raise investment capital in the regulated marketplace. The Commission expects companies to adhere to its rules and regulations and will bring enforcement actions like the one against Mylan NV when it believes that a company has failed to comply, particularly if that compliance failure either injured investors or posed a serious risk of harm to investors and the integrity of the stock market. While there are some specific reporting obligations imposed on listed companies, the Commission expects Self-Regulatory Organizations and their members to adhere to these important rules that help to ensure confidence in the exchanges and marketplace. Listed companies encounter various difficult issues, some of which have been addressed in this article, that require the advice of experienced and independent counsel. We believe that it is critically important to timely seek input and advice from outside the organization for many of these issues for the same reasons that Congress has moved to ensure that auditors are independent from the companies that they audit. Suggestions about best practices made in this article are those of the authors only, and do not constitute binding legal advice from them or their law firm.

Endnotes

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 filed an amended qui tam complai nt 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.

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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 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] Id. 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 incorrect 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(l). . . . [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(l).").

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:

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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 (6th 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).

[23] 17 C.F.R. §229.103.

[24] Clark, Securities Law Issues and Disclosure Considerations for Life Science Companies, at 12-53.

[25] J. Bradley Bennett & Andrew J. Brauer, *To Tell or Not to Tell: Weighing the Benefits and Pitfalls Self-Reporting Corporate Wrongdoing,* 38 SEC. REG. & LAW REP. No. 13, 526, 526 (Mar. 27, 2006).

[26] The Commission explains in Art. 1 of Regulation S-X, codified in 17 C.F.R. pt. 210, that the regulation sets forth "the form and content of and requirements for financial statements required to be filed as a part of . . . Registration statements under the Securities Act of 1933," and the form and content and requirements for financial statements required to be filed as a part of "annual or other reports under sections 13 and 15(d)," and, as a part of "proxy and information statements under section 14 of the Securities Exchange Act of 1934." Reg. S-X, Art. 1(a)(1), (2).

[27] *See* Clark, Securities Law Issues and Disclosure Considerations for Life Science Companies, at 12-55.

[28] *See* id.

[29] *See* id. at 12-61

[30] In re: EpiPen (Epinephrine Injection, USP) Marketing, Dkt. 896 (D. Kan., Aug. 20, 2018).

[31] *See* Dan Mangan, "Congress pushes Mylan for a lot more details on EpiPen profit," available at https://www.cnbc.com/2016/10/03/congress-pushes-mylan-for-a-lot-more-details-on-epipen-profit.html.

[32] *See* "EpiPen Price Increases," C-Span (Sept. 21, 2016), available at https://www.c-span.org/video/?415549-1/mylan-inc-ceo-heather-bresch-testifies-epipen-price-increases.

[33] *See*, e.g., "Cleary Gottlieb Discusses SEC Action for Non-Disclosure of DOJ Investigation," The CLS Blue Sky Blog (Oct. 15, 2019) ("The premature disclosure of what may turn out to be a baseless investigation (perhaps instigated by a person with a grudge or self-interest) can needlessly cause internal disruption, complicate an internal investigation, unnecessarily alarm current shareholders, and — in the worst case — lead to a cascade of events that might cause a company to settle even a meritless case to achieve closure in the public domain."), available at cisbluesky.law.columbia.edu/2019/10/15/cleary-gottlieb-discusses-sec-action-for-non-disclosure-of-doj-investigation/.

[34] See 31 U.S.C. § 3729 et seq.

[35] DOJ Justice Manual at 9-11.151 (Advice of "Rights" of Grand Jury Witnesses).

[36] "Guest Post: The Nuts & Bolts of SEC Investigations & Enforcement," The D& O Diary (Jan. 17, 2017), available at https://www.dandodiary.com/2017/01/articles/securities-laws/guest-post-nuts-bolts-sec-investigations-enforcement/.

[37] *See* id. The Wells Process involves the issuance of a Wells Notice that describes the SEC's recommendation of charges and their bases.

[38] Jeffrey B. Coopersmith, "Is There a Duty to Disclose an SEC Wells Notice?," David Wright Tremaine LLP (Oct. 2012), available at https://www.dwt.com/insights/2012/10/is-there-a-duty-to-disclose-an-sec-wells-notice. See Richman v. Goldman Sachs Group, Inc., 868 F.Supp.2d 261, 274-75 (S.D.N.Y. June 21, 2012) ("Plaintiffs ... argue that Defendants had an affirmative legal obligation to disclose their receipt of Wells Notices under Regulation S–K, Item 103, FINRA and NASD Rules. There is nothing in Regulation S–K, Item 103 which mandates disclosure of Wells Notices. Item 103 does not explicitly require disclosure of a Wells Notices, and no court has ever held that this regulation creates an implicit duty to disclose receipt of a Wells Notice. When the regulatory investigation matures to the point where litigation is apparent and substantially certain to occur, then 10(b) disclosure is mandated, as discussed above. Until then, disclosure is not required. Moreover, even if Goldman had such a duty here, "[i]t is far from certain that the requirement that there be a duty to disclose under Rule 10b–5 may be satisfied by importing the disclosure duties from [an] S–K

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[regulation].") In re Canandaigua Sec. Litig., 944 F.Supp. 1202, 1210 (S.D.N.Y.1996) (addressing S–K regulation 303).

[39] "The plaintiffs contend that the failure to disclose a government investigation is actionable. But a government investigation, without more, does not trigger a generalized duty to disclose. See In re UBS AG Sec. Litig., No. 07–cv–11225 (RJS), 2012 WL 4471265, at *31 (S.D.N.Y. Sept. 28, 2012), aff'd sub nom., City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG, 752 F.3d 173 (2d Cir.2014) ('Indeed, absent an express prior disclosure, a corporation has no affirmative duty to speculate or disclose uncharged, unadjudicated wrongdoings or mismanagement, illegal internal policies, or violations of a company's internal codes of conduct and legal policies.') (internal citations and quotation marks omitted))."

[40] Gideon Mark and Thomas C. Pearson, "Corporate Cooperation During Investigations and Audits," 13 STAN. J. L. BUS. & FIN. 1, 23 (2007).

[41] In re Standards Relating to Listed Company Audit," Release No. 8220, 79 S.E.C. Docket 2876, 2003 WL 1833875 *50 (2003)

[42] W. R. Koprowski, Steven J. Arsenaulty, and Michael Ciprianoz "Financial Statement Reporting of Pending Litigation: Attorneys, Auditors, and Difference of Opinions,"15 FORDHAM J. CORP. & FIN. L. NO. 2, 439, 445 (2009)

[43] John Jett and Joshua C. Hess, "How Companies Can Keep Their Sensitive Information Away from Adversaries but Still Cooperate with Auditors," GA. BAR J. 27, 28 (Feb. 2017).

[44] As the SEC's Office of the Chief Accountant explains, in relevant part:

> The Sarbanes-Oxley Act of 2002 mandates that audit committees be directly responsible for the oversight of the engagement of the company's independent auditor, and the Securities and Exchange Commission (the Commission) rules are designed to ensure that auditors are independent of their audit clients. . . .
>
> * * *
>
> Certain relationships between audit firms and the companies they audit are not permitted. These include:
>
> - Employment relationships. A one-year cooling off period is required before a company can hire certain individuals formerly employed by its auditor in a financial reporting oversight role. The audit committee should also consider whether the hiring of personnel that are or were formerly employed by the audit firm might affect the audit firm's independence.
> - Contingent Fees. Audit committees should not approve engagements that remunerate an independent auditor on a contingent fee or a commission basis. Such remuneration is considered to impair the auditor's independence.
> - Direct or material indirect business relationships. Audit firms may not have any direct or material indirect business relationships with the company, its officers, directors or significant shareholders. Thus, audit committees should consider whether the company has implemented processes that identify such prohibited relationships.
>
> Certain Financial Relationships. Audit committees should be aware that certain financial relationships between the company and the independent auditor are prohibited. These include creditor/ debtor relationships, banking, broker-dealer, futures commission merchant accounts, insurance products and interests in investment companies.

"Audit Committees and Auditor Independence," *available at* https://www.sec.gov/info/accountants/audit042707.htm

[45] A good discussion of these issues appears in Lane Powell PC, "Disclosures Redux-Outside Auditors and Attorney Work-Product," Lexology (March 29, 2018) ("Most courts have concluded that disclosures to outside auditors do not have the requisite adversarial relationship for waiver. See, e.g., SEC. v. Schroeder [No. C07–03798 JW (HRL), 2009 WL 112557, at *8 (N.D. Cal. April 27, 2009) ("Courts are split over … whether disclosure to an independent auditor waives protection. Some courts find a waiver on the ground that the auditor acts as a "public watchdog" with interests … not necessarily aligned with … the company being audited. See, e.g., Medinol, Ltd. v. Boston Scientific Corp., 214 F.R.D. 113, 116 (S.D.N.Y.2002) (concluding that work product protection as to the special litigation committee's materials was waived when the information was disclosed to an outside auditor); Diasonics Securities Litig., No. C83–4584, 1986 WL 53402 (N.D. Cal., June 15, 1986) (concluding that the work product protection did not apply to documents disclosed to an auditor acting as a public accountant rather than as a consultant). Cf. Samuels v. Mitchell, 155 F.R.D. 195, 200–201 (N.D.Cal.1994) (finding no waiver where documents were disclosed to an auditor that acted as a consultant rather than as a public accountant). Nevertheless, under the circumstances presented here, this court finds that the better view … is that espoused by Merrill Lynch & Co. v. Allegheny Energy, Inc., 229 F.R.D. 441 (S.D.N.Y.2004). That court concluded that disclosures to outside auditors do not have the "tangible adversarial relationship" requisite for waiver. Id. at 447.")]; In re JDS Uniphase Corp. Sec. Litig.; SEC v. Roberts; Merrill Lynch & Co. v. Allegheny Energy, Inc. However, other courts have concluded that disclosures to outside auditors do amount to a waiver. See, e.g., Middlesex Ret. Sys. v. Quest Software, Inc.; Medinol, Ltd. v. Boston Scientific Corp.; Samuels v. Mitchell. The only federal appellate court to have ruled on the question is the D.C. Circuit in United States v. Deloitte LLP [610 F.3d 129 (D.C. Cir. 2010) (aff'g district court's decision that Dow did not waive work product privilege when it produced three documents to Deloitte in connection with an ongoing tax litigation between Dow and the government)], which

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concluded that work product protections are not waived by disclosure to independent auditors., at https://www.lexology.com/library/detail.aspx?g=d80ecd11-c9a3-4c75-9eee-52ea1cea6d72.

[46] *See* Koprowski, Arsenaulty, and Ciprianoz "Financial Statement Reporting of Pending Litigation: Attorneys, Auditors, and Difference of Opinions,"15 FORDHAM J. CORP. & FIN. L. at 453 ("Whether a lawyer refuses to furnish all … information requested in an inquiry letter or does not provide enough evidence for the auditor to "support management's assertions about the nature of a matter involving an uncertainty and its presentation or disclosure in the financial statements, the auditor should consider the need to express a qualified or to disclaim an opinion because of a scope limitation … if sufficient evidential matter does or did exist but was not available to the auditor." [REPORTS ON AUDITED FINANCIAL STATEMENTS, Statement on Auditing Standards No. 98, § 508.31 (Am. Inst. of Certified Pub. Accountants 1989).

[47] *See*, e.g., Lisa Vicens & Daniel D. Queen, "Audits and Adversaries: Making Disclosures to Your Auditors Without Waiving Your Privilege," Cleary M&A and Corporate Governance Watch" (May 1, 2017), available at https://www.clearymawatch.com/2017/05/audits-adversaries-making-disclosures-auditors-without-waiving-privilege/ (recommending steps to take before disclosing any work product to outside auditors).

[48] *See* id.

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