PUBLICATION

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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In the first part of this series of Client Alerts, we addressed some of the background issues associated with the Commission's enforcement action against Mylan N.V. that followed the large generic drug company's settlement of two qui tam suits for over $400 million dollars, then began examining a listed company's disclosure obligations under the federal securities laws. In this part, we examine the key regulations that mandate periodic and episodic disclosures and look at some more events that preceded the SEC's enforcement action against Mylan.

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).

Regulation S-K

"Item 103 of Regulation S-K[1] 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.'"[2] "This obligation also encompasses 'similar information as to any such proceedings known to be contemplated by governmental authorities.'"[3]

Regulation S-X

Item 303 of Regulation S-X, "Management's Discussion and Analysis" (MD&A),[4] 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, as no private cause of action is recognized for such violations, which is explained in *In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 403 (6 Cir. 1997).[5] 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).[6] 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, 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 investors 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.[7]

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; or 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*:

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 epinephrine 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.[8]

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. 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. 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 percent in seven years and defended the increases by saying that Mylan had expanded EpiPen's availability to consumers. 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.

Armed with the benefit of 20-20 hindsight, clearly Mylan should have been more liberal in 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.[9]

The final Client Alert in this series will conclude by offering practical advice for reporting companies about how to assess and respond to certain risks when assessing their disclosure obligations and examine how and why care needs to be used when providing any privileged information to outside auditors, and what can be done to minimize those risks.

[1] 17 C.F.R. §229.103.

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

[3] *Id*. (citing 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)).

[4] 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).

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

[6] See id.

[7] See Clark, *Securities Law Issues and Disclosure Considerations for Life Science Companies*, at 12-61.

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

[9] *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* http://clsbluesky.law.columbia.edu/2019/10/15/cleary-gottlieb-discusses-sec-action-for-non-disclosure-of-doj-investigation/.