

# Regulatory and Enforcement Alert

## SEC Enforcement Action Highlights Public Company Disclosure and Accrual Obligations Relating to Ongoing Government Investigations

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### Overview

Among the flurry of enforcement actions brought by the Securities & Exchange Commission in late September (coinciding with the agency's fiscal year end) was an important case bearing on the responsibility of public companies to disclose and properly accrue for ongoing government investigations. The SEC alleged that pharma company and EpiPen maker Mylan NV had waited too long to disclose the existence of a Justice Department investigation, and had improperly failed to establish a loss contingency for the matter—which was focused on whether Mylan had overcharged the government for EpiPen sales to Medicaid enrollees. The SEC also charged Mylan with having misstated the risks that another federal agency would conclude that Mylan misclassified EpiPen as a generic drug, a classification that ultimately would bear on the company's liability in the DOJ investigation.

Mylan settled the SEC's case by agreeing to pay a \$30 million civil penalty and to be enjoined from violating the reporting, books and records and non-scienter fraud provisions of the federal securities laws. The case highlights the care required as issuers assess the adequacy of their disclosures and loss contingencies when facing government investigations, especially as those investigations evolve and advance toward resolution.

### Background

The chronology of events set forth in the Commission's complaint is instructive:

- In 2013, the Centers for Medicare and Medicaid Services ("CMS") began questioning Mylan's classification of EpiPen as a generic drug.
- In the fall of 2014, CMS informed Mylan that it had misclassified EpiPen and told Mylan to change the classification.
- Also in the fall of 2014, DOJ began investigating whether Mylan violated the False Claims Act by wrongly classifying EpiPen as a generic drug, which meant that Mylan overcharged the government for EpiPen sales to Medicaid enrollees.

- In November 2014, DOJ sent Mylan a subpoena for documents related to EpiPen. DOJ's investigation continued over the better part of the next two years, and Mylan continued to produce documents and information to DOJ.
- In October 2015, Mylan produced an analysis to DOJ showing that potential non-trebled damages to the government for a single quarter ranged from \$12 to \$42 million.
- In June 2016, Mylan provided additional data to DOJ, including an estimate that non-trebled damages for 2015 alone would be between \$114 and \$260 million.
- On July 29, 2016, Mylan offered to settle DOJ's putative claims under the False Claims Act for \$50 million.
- In October 2016, Mylan reached a settlement with DOJ in which the company agreed to pay \$465 million.

### Mylan's SEC Filings

Mylan did not disclose CMS's determination in the fall of 2014 regarding EpiPen in the company's SEC filings in 2014 and 2015.<sup>1</sup> Instead, in the Risk Factors section of its 2014 and 2015 10-K filings, the company disclosed only that CMS "may" disagree with the company's classification of EpiPen as a generic drug.

Mylan did not disclose the existence of the DOJ investigation and did not accrue any amount for it until Mylan announced, in October 2016, that it had settled the matter. The company had filed a 10-Q without mentioning or accruing for the investigation as recently as August 9, 2016, after the company had made an offer of settlement that included a \$50 million payment.

### The SEC's Allegations

Under Accounting Standard Codification ("ASC") 450, an issuer must disclose a loss contingency if a material loss is at least "reasonably possible"—*i.e.*, has more than a slight (but less than a likely) chance of coming to fruition. And an issuer must record an accrual (a charge against income in its financial statements) for a material loss that is both probable and reasonably estimable. The SEC's complaint against Mylan alleged violations of both these standards.

- **Disclosure/"reasonably possible"**: According to the SEC, Mylan violated the "reasonably possible" disclosure requirement in its periodic filings that followed on the heels of the company's production to DOJ of an analysis showing that damages for one quarter ranged from \$12 to \$42 million. The SEC found that Mylan failed to disclose (i) the nature of the contingency resulting from the investigation of whether Mylan incorrectly classified EpiPen, and (ii) its best estimate of the range of reasonably possible loss.
- **Accrual/"probable and reasonably estimable"**: According to the SEC, Mylan started violating the accrual requirement by the time it furnished DOJ a damages estimate for 2015 alone of between \$114 and

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<sup>1</sup> By late September 2016, CMS publicly commented that it "expressly advised" Mylan of the improper classification. *U.S. agency told Mylan that EpiPen was misclassified*, REUTERS (Sep. 28, 2016), <https://www.reuters.com/article/us-congress-mylan-nl-idUSKCN1tYIX5>.

\$260 million, and then offered to settle for \$50 million. By that time, the SEC asserted, Mylan should have known that a material loss was probable. And Mylan also should have known that the amount of the probable loss was reasonably estimable, as Mylan had sufficient information to estimate a range of losses. Mylan should have accrued its best estimate of the loss—or, if it did not have a best estimate, the minimum amount of the loss within the estimated range of losses.

Further, the SEC alleged that Mylan’s risk factor disclosures in its 2014 and 2015 10-Ks were misleading because the company merely stated that it faced the *risk* that CMS could take the position that Mylan had mischaracterized EpiPen as generic, when in fact Mylan knew that CMS had already taken that position.

## Takeaways

The Mylan case is a reminder that that issuers must continually assess and reassess their exposures in government investigations (as well as other litigation matters) to ensure they are meeting their disclosure and accounting obligations. Among other things:

- An investigation may need to be disclosed if it could have a material impact on the issuer’s financial performance or business. Moreover, such potential impact need not be limited to the strict financial terms of any reasonably possible settlement. Issuers should be mindful of the reputational and other collateral consequences that could arise from a government investigation.
- Disclosure and accounting obligations may change as a government investigation develops. Material settlement offers are especially critical milestones in government investigations because such offers may evidence (i) probable liability, and (ii) at least the “low end” of the range of what is estimable for purposes of recording accruals. Similarly, a Wells notice from the SEC or an analogous notice from another agency is a good occasion for an issuer to reassess its disclosures and accruals related to the underlying matter, as such a notice may indicate that the agency is more likely to bring an enforcement case.
- It is important that an issuer engage in a robust dialogue with its independent auditor about the status and potential materiality of a government investigation, especially as the investigation matures.
- Finally, as the SEC has made clear in other cases (*see, e.g.*, the SEC’s 2018 case against Yahoo!<sup>2</sup>), disclosure that something “may” happen may not suffice when the issuer knows that very event has already come to fruition. Issuers should be particularly vigilant that their risk disclosures do not become stale in this regard.

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<sup>2</sup> In April 2018 the SEC fined Yahoo! \$35 million for failing to disclose a significant, known data breach. In the two years following the breach, Yahoo! filed several quarterly and annual reports that said the company faced only the risk of data breaches. *Altaba, Formerly Known as Yahoo!, Charged With Failing to Disclose Massive Cybersecurity Breach; Agrees To Pay \$35 Million*, SEC. & EXCH. COMM’N (Apr. 24, 2018), <https://www.sec.gov/news/press-release/2018-71>.

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