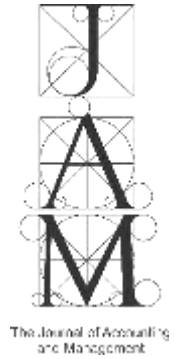

Mylan Fraud: Accounting and Disclosure Considerations

Devon Baranek[1]

Abstract: This teaching case outlines how Mylan, N.V., a global pharmaceutical company, recently paid nearly $500 million to settle investigations with the Securities and Exchange Commission and Department of Justice alleging multiple accounting and disclosure failures stemming from its classification of EpiPen as a generic drug. This misclassification allowed Mylan to underpay Medicaid rebates by hundreds of millions of dollars and significantly raise the price of EpiPen in the private marketplace. The SEC complaint details how Mylan violated generally accepted accounting principles and other securities laws by failing to disclose the DOJ investigation to investors or accrue for the potential loss contingency, causing earnings to be materially overstated. Mylan also included misleading statements in its disclosures with respect to the government's position during the investigation. The case demonstrates the importance of professional judgement and the appropriate application of generally accepted accounting principles for public companies. Misclassifying EpiPen allowed Mylan to profit at the expense of the Medicaid, by allowing Mylan to significantly increase the drug price in the private market while avoiding paying the corresponding rebate obligations to Medicaid. The case illustrates how corporate greed can drive fraud, how fraud is strategically committed, and how it is eventually exposed and prosecuted.

Keywords: Accounting fraud, loss contingency, disclosure violations, material misstatements

JEL Classification: G01

1. Introduction

Mylan N.V. is a global pharmaceutical company headquartered in Canonsburg, PA that offers over 7,500 products to consumers, retailers, pharmacies, governments and physicians in more than 165 countries. Its product portfolio includes brand and generic drugs, biosimilars[2], and over-the-counter remedies (Mylan 2020). Mylan is publicly traded on the NASDAQ, included on the Dow Jones U.S. Pharmaceuticals Index and reported more than $11.4 billion in sales in 2018 (Mylan 2018).

[1]Ph.D., CPA, Assistant Professor of Accounting, Norm Brodsky College of Business, Rider University, Lawrenceville, N.J., USA. Corresponding author: dbaranek@rider.edu.

[2] A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product (FDA 2020).

2. Case Details

2.1 Epipen Classification and Medicaid

Mylan Specialty is a sub-segment of Mylan's pharmaceutical business that competes in the respiratory and severe allergy market. A significant portion of Mylan Specialty's revenue is derived from the sale of EpiPen. Mylan has the worldwide rights to EpiPen, an epinephrine auto-injector used to treat severe allergic reactions that has been available since the 1980s. EpiPen was Mylan's largest drug by sales and profit, and became the first product to reach $1 billion in annual sales (Mylan 2014).

From 2014-2016, approximately 20% of Mylan's annual EpiPen sales were to Medicaid patients. Drug pricing for Medicaid is a complicated process, determined by Congress and the Centers for Medicare & Medicaid Services (CMS). In order to be covered by Medicaid, pharmaceutical companies must participate in the Medicaid Drug Rebate Program (MDRP) to help offset the cost of drugs dispensed to Medicaid patients (Medicaid 2020). As a participant of the MDRP, Mylan was required to submit pricing information on a quarterly basis to the Centers for Medicare and Medicaid Services, and pay quarterly rebates to Medicaid based on the units of EpiPen dispensed to Medicaid beneficiaries (DOJ 2017a).

An additional requirement of the MDRP is the classification of each drug sold through Medicaid as "non-innovator multiple source" drugs (generic drugs), or "single source"/ "innovator multiple source" drugs (branded drugs). Rebate rates paid by pharmaceutical companies to the government for generic drugs are much lower than rebates paid for branded drugs (SEC 2019a).

EpiPen had numerous branded-drug characteristics, including being approved by the Food and Drug Administration under a new drug application, lacking any therapeutically equivalent drugs, patent protection, significant advertising directed at end-users of the product, and a high price point. Despite these factors, Mylan classified EpiPen as a generic drug under the MDRP, starting in 2007 when it acquired EpiPen marketing rights from another company. The first company, and Mylan, based the classification on a single letter from a CMS employee that stated it was appropriate to classify EpiPen as generic drug in 1997 (SEC 2019a).

2.2 CMS Request and DOJ Investigation

In 2013, CMS began questioning Mylan's classification of EpiPen as a generic drug and twice requested the pharmaceutical company verify and update the classification. During this time, Mylan conducted an internal review and found that a competitive product was classified as a branded drug. By the end of 2014, CMS informed Mylan that it had misclassified EpiPen and that the 1997 letter should not be relied upon as guidance (SEC 2019a).

During 2014, a competing pharmaceutical company, Sanofi-Aventis, reported Mylan's EpiPen misclassification to the U.S. Attorney's Office. Sanofi was manufacturing its own epinephrine auto-injector drug at the time and was required to report it as a branded drug and pay higher Medicaid rebates. By 2016, Sanofi filed a claim under the whistleblower provision of the False Claims Act to expose the misclassification and related Medicaid rebate pricing issues (DOJ 2017b).

Concurrently, in November 2014, Mylan received a subpoena from the DOJ, leading to an investigation on its EpiPen classification, potential violations of the False Claims Act, and overcharging the government for EpiPen sales to Medicaid beneficiaries (DOJ 2017a). During this

time, Mylan also received inquiries from other federal and state government agencies, as well as members of Congress relating to the classification and pricing of EpiPen (Mylan 2016b).

The DOJ alleged that Mylan misclassified EpiPen as a "noninnovator multiple source drug" (generic) instead of a "single source" (brand) drug for Medicaid Rebate purposes from July 2010 through March 2017, which benefitted Mylan significantly by allowing it to underpay rebates owed to Medicaid (DOJ 2017a). Moreover, Mylan avoided paying an additional 13% rebate when it acquired the marketing rights to EpiPen in 2007 and raised the price approximately 400% (a rate much higher than inflation). EpiPen pricing was increased from $100 (per two-pack) in 2007 to over $600 in 2016, and if it had been classified as a branded drug an additional portion of the Medicaid sales would have been paid back to Medicaid (SEC 2019a).

On October 7, 2016, Mylan agreed to a $465 settlement with the DOJ and other government agencies to resolve the EpiPen misclassification and False Claims Act violations. As part of the settlement, Mylan agreed to reclassify EpiPen as an innovator (branded) drug effective April 1, 2017 (Mylan 2016b). Mylan also entered into a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General, requiring independent reviews of its practices relating to the MDRP (DOJ 2017b). The terms of the settlement did not include any finding of wrongdoing on the part of Mylan.

As part of the settlement, Mylan included a pre-tax charge of $465 in the third quarter of 2016 and revised its earnings guidance to $4.70-$4.90 per share, down from $4.85-$5.15 to reflect the financial implications of this change (Mylan 2016a). Additionally, the settlement resolved the allegations brought forth under the whistleblower provisions of the False Claims Act filed by Sanofi-Aventis, who was awarded approximately $38.7 million (DOJ 2017b).

3. SEC Investigation, Public Disclosures and Loss Contingency

The DOJ probe ultimately led to a related investigation by the SEC into accounting and disclosure violations associated with the Medicaid billing and the DOJ investigation itself. On July 29, 2019, Mylan disclosed in a public filing that it had reached an agreement-in-principle with the SEC in connection with the SEC's investigation of its public disclosures regarding the DOJ EpiPen settlement (Mylan 2019b). The SEC complaint focused on two major claims: 1.) that Mylan's disclosures on its 2014 and 2015 annual reports were misleading because the company made misleading statements with respect to the position CMS had taken on the EpiPen classification and 2.) that Mylan failed to disclose a material loss contingency relating to the DOJ investigation and also did not accrue the for loss based on the likelihood of the investigation resulting in a loss (SEC 2019a).

3.1 Misleading Public Disclosures

Public companies are required to "describe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations" in Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) on the annual report Form 10-K (17 CFR 229.303(a)(2). The SEC alleged that Mylan omitted material information and made misleading statements in its regulatory filings for 2014 and 2015. Item IA. "Risk Factors" includes information about the most significant risks that apply to the company. In connection with the DOJ investigation,

Mylan disclosed in 2014 and 2015 that, "…should there be ambiguity with regard to how to properly calculate and report payments – and even in the absence of such ambiguity – a governmental authority may take a position contrary to a position we have taken, and may impose or pursue civil and/or criminal sanctions" and that "There can be no assurance that our submissions will not be found by CMS or the VA to be incomplete or incorrect" (Mylan 2014, 2015).

These statements imply that CMS had not yet stated its position on the EpiPen classification, when it had specifically done so in October 2014 and requested that Mylan correct the error and reclassify EpiPen as a branded drug (SEC 2019a). Mylan's risk factor disclosures mislead investors about the potential severity and magnitude of the DOJ investigation.

3.2 Loss Contingency

Accounting Standards Codification (ASC) 450 provides guidance on the application of Generally Accepted Accounting Principles (GAAP) for loss contingencies. A loss contingency is "an existing condition, situation, or set of circumstances involving uncertainty as to possible loss to an entity that will ultimately be resolved when one or more future events occur or fail to occur" (ASC 450-20-20). ASC 450 also provides specific examples of loss contingencies, including actual or possible claims and assessments and pending or threatened litigation (ASC 450-20-05-10). By this definition, the DOJ investigation and potential claims and litigation that would result are considered a loss contingency.

When a loss contingency exists, the likelihood that the future event(s) will confirm the loss can range from probable to remote and must be analyzed. If the loss is at least "reasonably possible" (more than remote but less than likely), GAAP requires disclosure of the loss contingency. For Mylan, the liability resulting from the misclassification of EpiPen qualifies as a material loss contingency and should have been disclosed to investors. Additionally, ASC 450 requires that an estimated loss from the contingency should be accrued if the outcome is probable (likely to occur) and the amount of the loss can be reasonably estimated (ASC 450-20-25-2).

According to the SEC, Mylan knew by the end of Q3 that the likelihood of a material loss from the EpiPen classification was reasonably possible, but it failed to disclose this information or the range of potential loss on its Form 10-Q and Form 10-K during this time. In August, 2015, during the DOJ investigation, Mylan analyzed the financial impact of re-classifying EpiPen and estimated the potential damages owed for a single quarter of 2015 to range from $12-$42 million. Another analysis produced an estimate of $144-$260 million in damages for 2015 alone. Given these large estimates, Mylan knew that the total possible loss arising from the DOJ would be significantly higher than these amounts. By May 2016, Mylan had updated its estimated damages for 2015 to between $114 - $260 million (SEC 2019a). Throughout the 2014-2016 period, Mylan had sufficient information to estimate a range of losses and could have accrued the loss but chose not to, resulting in materially false and misleading filings that overstated earnings.

In July 2016, Mylan offered to settle with DOJ for $50 million. The DOJ rejected Mylan's offer but continued to negotiated a settlement. Despite the settlement attempt, Mylan still had not disclosed the DOJ investigation to its investors or accrued for the loss associated with the investigation in its financial statements. The $465 million settlement with the DOJ and related disclosure and accruals did not occur until October 2016.

In addition to the inaccurate books are records, Mylan also failed to maintain a system of internal accounting controls to ensure timely disclosure and accrual of the loss contingency associated with the

EpiPen classification throughout 2014-2016 period (SEC 2019a). The existence of these internal control weaknesses allowed the financial statements to be prepared without conformity to GAAP. During this time, both Mylan's management and external auditor assessed the company's internal control using the criteria outline in the 2013 Committee of Sponsoring Organizations of the Treadway Commission (COSO) Integrated Framework and concluded Mylan maintained effective internal control over financial reporting (Mylan 2015, 2016b).

3.3. Aftermath

In 2019, the SEC announced charges against Mylan for the accounting failures stemming from the EpiPen investigation. The SEC alleged that Mylan failed to disclose the DOJ probe to investors or disclose and accrue a liability for the potential loss. Mylan agreed to settle and pay a $30 million penalty (SEC 2019b).

Ultimately, misclassifying EpiPen as a generic drug for the Medicaid Drug Rebate Program was an illegal, expensive, anti-competitive decision and Mylan is still dealing with the consequences. The company paid nearly $500 million in fines to the DOJ and SEC, lost significant value in its share price, attracted unwanted scrutiny of regulators and investors for other EpiPen pricing issues, and caused significant reputational damage to the Mylan brand. The company's CEO Heather Bresch, the first female CEO of a Fortune 500 global pharmaceutical company, was very publicly criticized during Congressional hearings in 2016 and announced her retirement from Mylan in 2019 (Mylan 2019c). Additionally, there are several related lawsuits pending, including an antitrust lawsuit against Sanofi and federal and civil class actions from shareholders (Mylan 2019a).

This case serves as a reminder for other public companies that they must carefully consider whether, when and how to disclose pending investigations. The SEC established its expectation for earlier disclosure and contingency accrual, particularly when an investigation is related to a significant product, as was the case for Mylan. These accounting issues are complex and require significant judgement, particularly with regard to determining whether a loss is remote, reasonable possible or probable and estimating the amount or range of loss to disclose. Companies in the public eye need to tread especially lightly in these complex "grey" areas.

4. Discussion Questions

1. Briefly explain the alleged fraud. What happened at Mylan?
    a. How did CMS and the DOJ discover the issue?
    b. How much was Mylan able to benefit from the alleged fraud?
2. What are the two main complaints identified by the SEC in the investigation?
3. Explain how the fraud triangle applied here. List some of the opportunities, incentives and attitudes that allowed the misclassification of EpiPen and related accounting and disclosure issues to occur.
4. Search the FASB Accounting Standards Codification (ASC) and provide the definition (and citation) of a contingency.

5. According to GAAP, when should a contingency be disclosed?
6. ASC Topic 450 provides guidance on contingencies. What are the two conditions that, if met, require a company to accrue a loss contingency?
7. Briefly outline the timeline of events relating to the DOJ investigation and settlement. At what point was Mylan required by GAAP to disclose the potential loss related to the misclassification of EpiPen? At what point was Mylan required to accrue the loss contingency?
8. What was the financial impact of omitting the loss contingency for Mylan? What accounts were overstated or understated?
9. Mylan failed to devise and maintain a system of internal accounting controls sufficient to disclose and accrue for the potential loss related to the DOJ investigation, causing the financial statements to not conform with GAAP.
    a. Explain why effective internal controls (particularly over financial reporting) are necessary to provide reasonable assurance with respect to the reliability of financial reports.
    b. Describe the five integrated components of internal control outlined in *Internal Control – Integrated Framework (2013)* issued by COSO.
    c. Which of these components was weak or lacking at Mylan for the duration of the fraud?
10. Discuss some of the negative consequences for Mylan resulting from the case. Explain which of these is the most damaging for Mylan.
11. What are some of the aggravating factors of the case? Are there any mitigating factors to consider?
12. The misclassification of EpiPen as a generic drug and related Medicaid rebate issues were well known among the leadership at Mylan.
    a. What are some of the reasons senior executives or managers may participate in this type of fraud?
    b. How might managers encourage accountants and other staff to go along with this type of scheme?
    c. How might accountants or other employees resist this type of pressure from management?
    d. What are some of the professional resources are available for CPAs facing an ethical dilemma?
13. Mylan contended throughout the DOJ investigation that EpiPen was not misclassified, citing the 1997 Letter to support its position. The company provided documents and information to the DOJ over the 2014-206 period. Mylan executives, including those responsible for the preparation and review of financial statements were aware of the investigation and settlement negotiations but chose to support the company position that EpiPen be classified as a generic drug.
    a. How does a company determine whether a chosen reporting strategy is aggressive but still within GAAP, versus fraudulent financial reporting?

b. Review Mylan's Consolidated Balance Sheet as of December 31, 2016. Identify other accounts with balances that likely required significant judgement or estimation on the part of management. Describe the reasons why estimates and professional judgement are required for these accounts.

5. Suggested Solutions

1. Briefly explain the alleged fraud. What happened at Mylan?

   Mylan misclassified one of its largest products, EpiPen, as a generic drug despite it meeting several of the requirements for classification as a brand drug. By classifying EpiPen as generic, Mylan overcharged Medicaid by hundreds of millions of dollars. The SEC complaint details how Mylan violated generally accepted accounting principles and other securities laws by failing to disclose the DOJ investigation or accrue for the potential loss contingency, and by including misleading statements in its risk factor disclosures. Mylan ultimately paid almost $500 million to resolve the SEC and DOJ investigations.

   a. How did CMS and the DOJ discover the issue?

      CMS began questioning the classification of EpiPen in 2013 and by late 2014 it had informed Mylan that it was misclassified. A pharmaceutical competitor, Sanofi-Aventis, filed a lawsuit under the whistleblower provisions of the False Claims Act in 2016, alleging that Mylan knowingly misclassified EpiPen to avoid paying rebates to Medicaid.

   b. How much was Mylan able to benefit from the alleged fraud?

      Mylan overcharged Medicaid by hundreds of million of dollars. By its own estimates, potential damages owed to the government ranged between $114-260 million per year.

2. What are the two main complaints identified by the SEC in the investigation?

   I. Mylan's public disclosures in 2014 and 2015 were misleading about the potential severity and magnitude of the DOJ investigation.

   II. A public company facing a material loss contingency, such as one arising from a lawsuit or government investigation, is required under GAAP and securities laws to disclose the loss contingency if a loss is at least reasonably possible and record an accrual for the estimated loss (if the loss is probable and reasonably estimable)

3. Explain how the fraud triangle applied here. List some of the opportunities, incentives and attitudes that allowed the misclassification of EpiPen and related accounting and disclosure issues to occur.

   Opportunities:

   - Drug pricing for Medicaid is a complicated process. The size, scope and complexity of Medicaid itself makes it a high-risk program
   - Healthcare industry itself is complex

- No comparable equivalent for EpiPen and the demand is high – Mylan could function as a price-setter since it maintained a monopoly on auto-injectable epinephrine
- A new Enterprise Resource Planning (ERP) system was being implemented in certain countries during this period, which included modification and implementation of existing internal controls relating to its business and financial processes.

Incentives/Pressures:

- Pressure to meet or beat earnings expectations due to its recognition as a large, successful pharmaceutical company
- Medical industry competition is high
- Greed/desire to retain status as industry leader
- Bonus structure based on company performance targets

Attitudes/Rationalization:

- EpiPen had always been classified as generic drug in the past for Medicaid rebate purposes
- Mylan had the 1997 letter supporting its position
- No individuals were being hurt, it was only the government receiving less of a rebate.

4. Search the FASB Accounting Standards Codification (ASC) and provide the definition (and citation) of a contingency.

   A contingency is an existing condition, situation, or set of circumstances involving uncertainty as to possible gain or loss to an entity that will ultimately be resolved when one or more future events occur or fair to occur (ASC 450-10-55-1)

5. According to GAAP, when should a contingency be disclosed?

   A potential contingency should be disclosed if it is at least reasonably possible to estimate the amount and the effect of the change would be material (ASC 275-10-50-8). For a loss contingency, the disclosure should also include an estimate of the possible loss or range of loss, or state that an estimate can't be made (ASC 275-10-50-9).

6. ASC Topic 450 provides guidance on contingencies. What are the two conditions that, if met, require a company to accrue a loss contingency?

   The first condition is that information available indicates it is probable that an asset had been impaired or a liability had been incurred at the date of the financial statements, and the second condition is that the amount of the loss can be reasonably estimated (ASC 450-20-25-2).

7. Briefly outline the timeline of events relating to the DOJ investigation and settlement. At what point was Mylan required by GAAP to disclose the potential loss related to the misclassification of EpiPen? At what point was Mylan required to accrue the loss contingency?

   October 2014: CMS contacts Mylan to change EpiPen classification

   November 2014: Mylan receives first DOJ subpoena

   August 2015: Mylan estimates damages of $12 to $42 million for one quarter of 2015

May 2016: Mylan estimates damages of $114 million to $260 million for all of 2015

July 2016: Mylan offers $50 million settlement to DOJ.

August 2016: The DOJ rejects Mylan's offer. The parties continue to negotiate.

October 2016: Mylan announces $465 million settlement with DOJ and discloses investigation to investors

September 2019: SEC settlement announced

Mylan should have disclosed the loss contingency by at least August 2015, when it was clear the DOJ was investigating and that the impact of the potential loss would be material.

Mylan should have accrued the loss contingency by at least May 2016, when it was known that a material loss from the DOJ investigation was probable and that the amount (or range) was reasonably estimated. Mylan should have accrued its best estimate for the loss.

8. What was the financial impact of omitting the loss contingency for Mylan? What accounts were overstated or understated?

   Failure to accrue for the loss contingency materially overstated Mylan's reported earnings. Expenses were materially understated and net income was materially overstated.

9. Mylan failed to devise and maintain a system of internal accounting controls sufficient to disclose and accrue for the potential loss related to the DOJ investigation, causing the financial statements to not conform with GAAP.

   a. Explain why effective internal controls (particularly over financial reporting) are necessary to provide reasonable assurance with respect to the reliability of financial reports.

      A company's internal control over financial reporting includes policies and procedures that 1.) pertain to the maintenance of records which accurately and fairly reflect the transactions of the company, 2.) provide reasonable assurance that transactions are recorded as necessary to prepare the financial statements in accordance with GAAP and 3.) provide reasonable assurance regarding the prevention or timely detection of unauthorized use of company assets that may have a material effect on the financial statements.

   b. Describe the five integrated components of internal control outlined in *Internal Control – Integrated Framework (2013)* issued by COSO.

      Control Environment – includes standards, processes, and structures forming the foundation for carrying out internal controls across the organization. Tone at the top and expectations for conduct are set by management.

      Risk Assessment – dynamic process for identifying and assessing risks to the achievement of company objectives.

      Control Activities – the actions established through policies and procedures that help ensure management directives to mitigate risks and achieve objectives

      Information and Communication – management obtains or generates and utilizes relevant and quality information to support the functioning of internal control. Communication is continual and can be provided, shared and obtained internally or externally.

Monitoring Activities – ongoing or separate evaluations are used to determine whether each of the components of internal control are present and functioning.

c. Which of these components was weak or lacking at Mylan for the duration of the fraud?

The control environment at Mylan was poor – the board of directors and senior management were all aware of the questionable classification of EpiPen as generic and compromised the integrity and ethical values of the company by failing to consider reclassifying the drug, disclosing the DOJ investigation, or properly applying GAAP to the loss contingency.

Information and Communication –Mylan's controls required quarterly discussions of significant contingencies by its financial and legal teams, but the controls failed to require material information to be provided to the teams. Members of the financial team evaluating the potential loss contingency were not informed of some material information relating to the DOJ investigation.

10. Discuss some of the negative consequences for Mylan resulting from the case. Explain which of these is the most damaging for Mylan.

- $465 million DOJ fine
- $30 million SEC fine
- Mylan had to reclassify EpiPen as a branded drug and will have to pay Medicaid much higher rebates going forward.
- Litigation:
    - EpiPen Federal Securities litigation - class action complaints from shareholders
    - EpiPen Civil Litigation – filed
- Mylan had to agree to a mandatory corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services which requires an independent review of Mylan's practices relating to the MDRP. There is also additional accountability for Mylan board members and executives.
- The DOJ investigation drew the attention of other regulatory agencies
    - The SEC accounting disclosure violations
    - The FTC Bureau of Competition investigation anticompetitive practices in the market for epinephrine auto-injectors
    - EpiPen State Attorney General Investigations
    - U.S. Congress/State requests for information and documents
- Mylan's longtime CEO Heather Bresch stepped down in 2016

11. What are some of the aggravating factors of the case? Are there any mitigating factors to consider?

Aggravating factors:

- EpiPen was Mylan's largest revenue and profit generating product and the potential for a material loss was known by at least Q3 of 2015.

- Mylan's decision to raise the price of EpiPen drew additional scrutiny and caused a public outcry. The price hike also provokes political attention and eventually led to congressional hearings.
- Mylan's failure to disclose the EpiPen investigation was inconsistent with its practice of disclosing other investigations, including a DOJ investigation relating to the marketing, pricing and sale of Doxycycline, and an SEC investigation regarding related party matters.
- Mylan was able to come up with estimates of the potential damage

Mitigating factors:

- Mylan had the 1997 letter so there was some documented support for its position on EpiPen.
- Mylan cooperated with the DOJ and SEC during the investigations.

12. The misclassification of EpiPen as a generic drug and related Medicaid rebate issues were well known among the leadership at Mylan.

    a. What are some of the reasons senior executives or managers may participate in this type of fraud?

    Managers or senior executives face pressure to meet earnings expectations from analysts, shareholders, creditors, etc. Additionally, the bonus structure of public companies may often revolve around meeting or beating these types of targets. There may also be a reputation component for executives, who want to be seen as successful for potential future job opportunities, board seats, etc.

    b. How might managers encourage accountants and other staff to go along with this type of scheme?

The status of senior management can be intimidating to lower level employees and influence them to comply with potentially illegal requests. The threat of job loss or transfer, lack of promotion or bonus, etc., makes it especially difficult for lower level employees to resist pressure from the top. Lower level employees may also perceive executives to be more "business savvy" or knowledgeable about a situation and accept requests they may not completely understand.

    c. How might accountants or other employees resist this type of pressure from management?

        - Consider professional standards (for example search the FASB Codification and highlight a lack of compliance with GAAP to support an accounting position).
        - Review the Code Ethics governing the conduct of directors, officers and employees.
        - Consult with other employees or sources of knowledge (for example, call the state board of accountancy or state accounting association)

    d. What are some of the professional resources are available for CPAs facing an ethical dilemma?

        - American Institute for Certified Public Accountants (AICPA) – maintains a Code of Professional Conduct and provides additional ethics resources, answers FAQs, etc.

- Individual state boards of accountancy – in Pennsylvania where Mylan was headquartered, the PICPA maintains the AICPA Code of Ethics and Conduct and includes additional ethics guidance.
- National Association of State Boards for Accountants (NASBA) – provides resources for individual state boards of accounting.
- SEC Office of the Chief Accountant (OCA) – encourages public companies to consult with OCA on accounting, financial reporting or auditing questions. Questions concerning the application of GAAP are typically sent to the OCA.
- Public Company Accounting Oversight Board (PCAOB) – maintains ethics and independence rules for auditors, with a focus on independence, integrity and objectivity.

13. Mylan contended throughout the DOJ investigation that EpiPen was not misclassified, citing the 1997 Letter to support its position. The company provided documents and information to the DOJ over the 2014-206 period. Mylan executives, including those responsible for the preparation and review of financial statements were aware of the investigation and settlement negotiations but chose to support the company position that EpiPen be classified as a generic drug.

    a. How does a company determine whether a chosen reporting strategy is aggressive but still within GAAP, versus fraudulent financial reporting?

    Student responses will vary but should mention professional judgement on the part of management and accountants. Other factors to consider include industry averages, historical trends, prior litigation or enforcement action by the SEC or other regulatory agency, or the advice of area-specific experts.

    b. Review Mylan's Consolidated Balance Sheet as of December 31, 2016. Identify other accounts with balances that likely required significant judgement or estimation on the part of management. Describe the reasons why estimates and professional judgement are required for these accounts.

- Accounts receivable, net – this balance would be affected by management estimation of the allowance for doubtful accounts;
- Employee Receivables;
- Property, plant and equipment, net – this balance would be affected by depreciation computations for property, plant and equipment. The estimation of useful lives and salvage values directly impact the calculation of depreciation;
- Intangible assets, net – this balance is stated at cost less accumulated amortization. Purchases of developed products or licenses are accounted for as intangible assets. Management periodically reviews the original estimated useful lives of intangible assets and makes adjustments when appropriate;
- Goodwill – the original valuation of goodwill is directly impacted by estimates of the underlying market values of assets acquired. Management is also responsible for evaluating whether or not goodwill is impaired at least annually or more frequently if events or circumstances change.

6. Teaching Notes

6.1 Intended Audience and Learning Objectives

This case illustrates the important role of trust and reputation in corporate America, particularly in the pharmaceutical sector. Because EpiPen is a potentially lifesaving, globally distributed product, the level of student interest in the case is high. Mylan provides a recent example of how corporate greed can drive fraud, how fraud is strategically committed, and how it is eventually exposed and prosecuted.

This case is appropriate for intermediate or upper-level undergraduate financial accounting courses as well as graduate courses. It can be used during the coverage of a key financial accounting topic – accounting for contingencies. It would also complement class discussion about corporate fraud, internal control over financial reporting, professional judgement and ethics in the profession.

Six learning objectives are emphasized and mapped to each of the discussion questions in Table 1. First, students will explain what happened at Mylan with the EpiPen investigation and explain how the company's accounting and disclosure choices violated GAAP. Second, students will apply the fraud triangle and describe some of the incentives, opportunities and attitude conditions that existed at Mylan. Third, students will identify the negative consequences associated with financial reporting fraud and consider the implications for the different stakeholders of the company. Fourth, students will research the FASB Accounting Standard Codification to determine the appropriate accounting treatment for accruing and disclosing a contingency. Fifth, students will consider the role of internal control in connection with the prevention and detection of fraud. Sixth, students will identify ethical issues arising in the case and discuss the importance of professional judgement in accounting.

6.2 Implementation Guidance

It is recommended that this case be administered concurrent with classroom coverage of current liabilities and contingencies, internal control over financial reporting, ethics and liability issues and professional judgement. The research requirements necessitate that students are familiar with how to search and interpret the FASB Accounting Standards Codification, therefore a review of how to navigate the regulatory guidance is also suggested. Students must also be familiar with the internal control framework outlined by COSO. To enhance the student learning process, the case should be assigned as an individual project so that each student has the opportunity to navigate, interpret and apply the regulatory guidance.

After the case is assigned, the instructor should incorporate a brief (15-20 minute) class discussion to give students the opportunity to ask questions or clarify any facts of the case. Some of the case details are complicated (for example, the Medicaid rebate process) or include industry specific terminology (generic vs branded drugs) or legal terminology (False Claims Act, whistleblower provisions, civil investigations, etc.). Following this overview, students should be given a week outside of class to complete the case questions. The case should take about 90-120 minutes for students to complete.

On the due date, the entire class period (60-90 minutes) should be used to discuss the case solutions. Depending on the focus of the class, more time can be spent emphasizing different elements of the case, from searching the FASB ASC for the appropriate definition and accrual of a contingent liability to debating the professional judgement exercised by Mylan's accounting team and examining the ethical ramifications. The case provides flexibility in tailoring to the specifics of the course at a given

institution. Instructors may also choose to provide students with some of the additional resources included in Table 2 to reduce the level of difficulty for several of the discussion questions.

The case takes approximately 20-30 minutes each to grade. To avoid arduous grading burdens, the case questions can be divided so that some are completed individually (for example, DQ #1-7) while other questions are assigned to pairs or groups (DQ #8-14). Table 2 provides links to several resources that faculty may utilize or share with students.

Table 1. Learning Objectives Mapped to Discussion Questions

Learning Objectives	**Discussion Questions**
(1) Students will explain what happened at Mylan relating to the accounting and disclosure of the EpiPen investigation and how it violated GAAP	Q(1); Q(2); Q(4); Q(5); Q(7); Q(8)
(2) Students will describe examples of incentive, opportunity and attitude conditions (the fraud triangle) that were present at Mylan.	Q(3); Q(9)
(3) Students will identify the negative consequences associated with financial reporting fraud and consider the implications for Mylan's various stakeholders.	Q(10); Q(11)
(4) Students will research the regulatory guidance to determine the appropriate accounting treatment for accruing and disclosing a contingency	Q(4); Q(5); Q(6)
(5) Students describe the role of implementing and maintaining a system of internal controls in connection with the prevention and detection of fraud.	Q(3); Q(9)
(6) Students will identify ethical issues arising in the case and discuss the importance of professional judgement in accounting	Q(11); Q(12); Q(13)

Table 2. Links to Additional Resources

Resource	**Website Link**
SEC Complaint against Mylan	https://www.sec.gov/litigation/complaints/2019/comp-pr2019-194.pdf
FASB Accounting Standards Codification	https://asc.fasb.org/home
Mylan's 2016 10-K	https://investor.mylan.com/static-files/8bf772a1-467f-46d4-80db-f2fe99b44f99
COSO Internal Control - Integrated Framework - Executive Summary	https://www.coso.org/Documents/990025P-Executive-Summary-final-may20.pdf
AICPA Code of Professional Conduct	https://pub.aicpa.org/codeofconduct/Ethics.aspx
PCAOB Ethics and Independence	https://pcaobus.org/Standards/EI/Pages/default.aspx
PICPA Professional Ethics	https://www.picpa.org/keep-informed/professional-ethics
National Association of State Boards of Accountancy	https://nasba.org/
Medicaid Drug Rebate Program	https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html

References

Accounting Standards Codification (ASC) (450) (2019). Topic 450, Contingencies. *Financial Accounting Standards Board*. Retrieved from: http://www2.aaahq.org/asc.

Code of Federal Regulations (CFR) (2019). 17 CFR 229.303 (Item 303) *Management's discussion and analysis of financial condition and results of operations*. Retrieved from: https://www.law.cornell.edu/cfr/text/17/229.303.

Code of Federal Regulations (CFR) (2019b). Regulation S-K. Title 17, Chapter II, Part 229, Subpart 105, "Risk Factors". Retrieved from: https://www.ecfr.gov/cgi-bin/text-idx?amp;node=17:3.0.1.1.11&rgn=div5#se17.3.229_1105.

Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013). *Internal Control – Integrated Framework Executive Summary*. Retrieved from: https://www.coso.org/Documents/990025P-Executive-Summary-final-may20.pdf.

Department of Justice (DOJ) (2017a). *Mylan Settlement Agreement*. Press Release, August 17, 2019. Retrieved from: https://www.justice.gov/opa/press-release/file/990736/download.

DOJ (2017b). *Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates*. Press Release, August 17, 2019. Retrieved from: https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates.

Medicaid (2020). *Medicaid Drug Rebate Program*. Retrieved from: https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html.

Mylan (2014). *Form 10-K*. Retrieved from: https://investor.mylan.com/node/26941/html.

Mylan (2016a). *Press Release "Mylan Agrees to Settlement on Medicaid Rebate Classification for EpiPen Auto Injector*". October 7, 2016. Retrieved from: http://newsroom.mylan.com/2016-10-07-Mylan-Agrees-to-Settlement-on-Medicaid-Rebate-Classification-for-EpiPen-Auto-Injector.

Mylan (2016b). *Form 10-K*. Retrieved from: https://investor.mylan.com/static-files/8bf772a1-467f-46d4-80db-f2fe99b44f99.

Mylan (2018). *Form 10-K*. Retrieved from: https://investor.mylan.com/static-files/ed066de0-8491-4327-a044-9bb136d5b8c3.

Mylan (2019a) *Form 10-K*. Retrieved from: https://investor.mylan.com/static-files/f2190c8a-38e2-492b-908e-7c160cc82361.

Mylan (2019b). *Form 8-K*. Retrieved from: https://investor.mylan.com/static-files/e210da5f-92e7-4301-9875-c2187b7a15b0.

Mylan (2019c). *Statement from Mylan's Board of Directors Regarding Retirement of CEO and Board Member Heather Bresch in Conjunction with the Combination of Mylan and Upjohn, a Division of Pfizer*. Press Release 29 July 2019. Retrieved from: http://newsroom.mylan.com/2019-07-29-Statement-from-Mylans-Board-of-Directors-Regarding-Retirement-of-CEO-and-Board-Member-Heather-Bresch-in-Conjunction-with-the-Combination-of-Mylan-and-Upjohn-a-Division-of-Pfizer.

Mylan (2020). *Web page*. Retrieved from https://www.mylan.com/.

Securities and Exchange Commission (SEC) (2019a). *Securities and Exchange Commission v. Mylan N.V*. Case 1:19-cv-02904, September 29, 2019. Retrieved from: https://www.sec.gov/litigation/complaints/2019/comp-pr2019-194.pdf.

Securities and Exchange Commission (SEC) (2019b). *Mylan to Pay $30 Million for Disclosure Accounting Failures Relating to Epipen*. Litigation Release No. 24621, September 27. Retrieved from: https://www.sec.gov/litigation/litreleases/2019/lr24621.htm.

U.S Food and Drug Administration (FDA) (2020). *Biosimilar and Interchangeable Products*. Retrieved from: https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#biosimilar.