

## **Mylan's Epi-cal breach at the top**

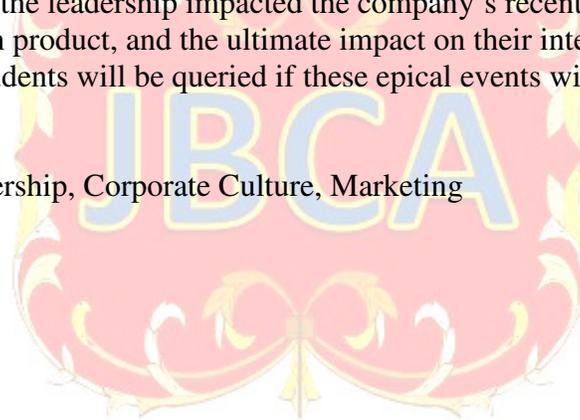
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### **ABSTRACT**

The senior leadership of an organization establishes the corporate culture, core values and principles that guide the decision-making process of the business. The CEO and Board of Directors at a major US pharmaceutical company may have established a tone at the top through their actions that has encouraged the company to take several controversial, even unethical actions. This case will describe the CEO and individual board activities, and ask students to determine appropriate checks and balances the company may have taken in relation to these situations. Students will also evaluate how the company's action or inaction to these challenges may have been influenced by the corporate culture. Students will be asked to weigh in on how the corporate culture and the leadership impacted the company's recent actions related to the marketing of their EpiPen product, and the ultimate impact on their internal and external stakeholders. Finally, students will be queried if these epic events will transform this company.

Keywords: Ethics, Leadership, Corporate Culture, Marketing



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## INTRODUCTION

The Tone at the Top is one of the most important controls available to an organization. If management sets a good example, employees will follow this lead. The Association of Certified Fraud Examiners notes: “Tone at the top refers to the ethical atmosphere that is created in the workplace by the organization's leadership. Whatever tone management sets will have a trickle-down effect on employees of the company. If the tone set by managers upholds ethics and integrity, employees will be more inclined to uphold those same values” In contrast, if senior managers do not value ethical integrity and choose to only focus on financial results, employees will follow suit (ACFE, 2016).

Tone at the top or an ethical culture is established by the leadership and incorporated into an organization's guiding values and principles. The core values of the institution are visible and a driving force in decision making. The ethical foundation provides the roadmap that is created and followed by the Board of Directors, the CEO and throughout the organization. This tone is a critical strategy, incorporated into the company's vision and leadership. The ethical climate is more than compliance; it establishes relevant roles for the stakeholders while mitigating reputation risk. Viewed as a real business challenge today, even a rumor of impropriety can damage a company's reputation. The tone at the top must also be communicated internally and externally with consistent messages. Organizational practices like recruiting and screening, socialization practices and reward systems must also be aligned to reflect the ethical ideals from senior management. Setting the right tone at the top often provides the proper direction for organizational excellence, resulting in positive financial performance and results.

Consider how the Tone at the Top is impacted by each of the following scenarios which all take place at Mylan, a pharmaceutical company.

## COMPANY BACKGROUND

Mylan N.V. is a global pharmaceutical company that produces and sells generic and specialty drugs. Mylan is domiciled in the Netherlands and has offices in Hatfield, U.K. and Canonsburg, Pennsylvania.

Founded in 1961 as a pharmaceutical distributor, Mylan began operations in West Virginia. Mylan's initial public offering (IPO) was in 1973 and now the company trades under the symbol MYL. Due to changes in the pharmaceutical industry, in the 1980s Mylan focused on generic drugs. They acquired other firms and flourished. Mylan is a global company of 40,000+ employees with revenue of \$9.45 billion and net income of \$800 million in 2015. They market over 2,700 separate products in 165 countries and territories, with over 50 manufacturing facilities to retail, wholesale, government and institutional customers.

One out of every 13 US prescriptions dispensed is a Mylan product (Mylan, 2016). Through a series of acquisitions, they now own Matrix Laboratories Limited (n/k/a Mylan Laboratories Limited), Merck KGaA's generics and specialty pharmaceuticals businesses, Abbott Laboratories' non-U.S. developed markets specialty and branded generics business, the female healthcare business of Famy Care Ltd., and India-based Agila. Specialties, a global leader in injectable products and an innovative respiratory technology platform.

Mylan has adopted a Code of Ethics for the CEO, CFO, and Corporate Controller, as well as a Business Code of Conduct and Ethics (Mylan Corporate Governance, 2016). Mylan espouses core values of innovation, integrity, reliability, service, and teamwork.

Mylan made the news in 2016 over the significant increase in the price of the EpiPen, one of the events this paper will review, along with previous media attention to issues with management qualifications, relocation of the company, and potential board of directors' conflict of interests.

## **Industry Background**

The pharmaceutical industry is comprised of companies involved in the marketing, research, and development of drugs and biologics. As stated in ReportLinker, the generic drug industry focuses on the sale and marketing of medication with the same active ingredients and dosage as name-brand drugs at a fraction of the cost. The savings can be up to 80-85% less, per the US Food & Drug Administration. Brand-name and generic drugs are subject to the same governmental standards. Generic drugs can be introduced to the market after the patent protections expire, creating a much less expensive alternative for consumers. Patents and intellectual property rights can extend to 20 years, but that includes the clinical trials as well. The Association of Accessible Medicines, formerly the Generic Pharmaceutical Association, states that 9 out of 10 drugs are now generic, saving consumers up to \$4 billion a week. The generic drug industry has provided additional drug choices for patients and increased competition. This market produced \$66 billion in revenue according to IBISWorld's Generic Pharmaceutical Manufacturing Market Research Report, released in April, 2016. The future looks promising with the aging population in the US and the limited competition among the top 4 generic drug manufacturers, led by Mylan.

## **Management Qualifications**

Heather Bresch, the current CEO at Mylan, has had an epic career and a meteoric rise to the top. According to Mylan's website, Ms. Bresch has served as Mylan's Chief Executive Officer ("CEO") since January 1, 2012. She learned the business over the past 25 years and was promoted frequently. Positions held include: Director of Government Relations (2002 – 2005); Senior Vice President of Corporate Strategic Development, Head of North American Operations, Chief Operating Office, Chief Integration Office, President (2009); CEO (2011 - present) and a member of the Board of Directors (2011 - present). Throughout her career with Mylan, Ms. Bresch has held roles of increasing responsibility in more than 15 functional areas. She is given credit for leading the successful integration of two transformational, international acquisitions – Matrix Laboratories Limited (n/k/a Mylan Laboratories Limited) and Merck KGaA's generics and specialty pharmaceuticals businesses.

Born and raised in West Virginia she has influential family ties. Her grandfather was a politician who served in the West Virginia legislature. Joe Manchin III, her father, has been a West Virginia politician for many years, and has served as governor of West Virginia and is currently a senior US Senator from West Virginia.

A graduate from West Virginia University (WVU) in 1991, Bresch holds a degree in political science and international relations. She was introduced to the CEO of Mylan, Milan Puskar, at a WVU football game in 1992, by her father who indicated she should work there. Mylan offered her a low level clerk position in a quality control section of a factory in Morgantown. She said she would try the position for a year, and started work in 1992.

Bresch was promoted to COO in 2008 and the press release indicated she had earned a MBA from WVU. A reporter at the Pittsburgh Post-Gazette called WVU to confirm her degree; they did not have a record of her degree. Her father was the West Virginia governor at the time; Milan Puskar, the Mylan CEO, was the largest donor to WVU (\$20 million in 2003 alone) and a major campaign contributor to the WVU Governor. The WVU president at the time was Mike Garrison, a former high school classmate of Ms. Bresch's and a longtime friend of the Manchin family (Urbina, 2008).

The controversy soon blossomed; WVU stated Ms. Bresch had only completed 22 of the required 48 credits for the Executive MBA degree. Various explanations were put forth as to how a MBA degree was awarded like whether work experience could be substituted for coursework, when the program was not completed by Bresch. A university investigation ensued that resulted in a 95-page report that resulted in WVU administrators revoking Bresch of her degree. As a result of the WVU investigation, Garrison, the WVU president, and two other school officials were fired. The WVU investigation report stated that administrators had given Bresch grades "pulled from thin air" because of her "high profile", but did not directly blame her or accuse her of lying about completing her coursework and/or earning the MBA (Urbina, 2008). Instead, the WVU report noted: "Taking the most charitable view of this claim, the Panel believes there may well have been a misunderstanding" (Wieczner, 2016). Bresch, however, is still sensitive to this subject, as noted in a rare discussion about this issue with Fortune magazine in 2016:

"I don't subscribe to it was a misunderstanding on my part," she said. "But I certainly to this day believe I did everything I needed to do to get my degree. "So I have not backed down from that. What I backed down from was continuing to fight because I thought enough damage had already been done," she continued. "Obviously it was a hurtful situation for everybody involved and I would hate that that happened. But I don't subscribe that it was a misunderstanding. I think it wasn't handled, and a lot of things compromised it not being handled the right way" (Wieczner, 2016).

Bresch retained her position as COO at Mylan, despite the retraction of her MBA degree by WVU. The Board determined that her degree wasn't a specific requirement for her position and business at Mylan continued as usual.

### **EpiPen Price Increases**

Mylan is not a stranger to scandal. Most recently, they have been embroiled in a significant dispute involving the soaring cost of their product Epi-pen and multiple stakeholders; their customers, the US government, insurance firms, benefits managers and the pharmaceutical industry association. The product involves epinephrine or adrenaline, a hormone produced by the body's adrenal glands. Epinephrine itself is very inexpensive, costing less than \$1 per milliliter, and less than 1/3 is contained in an Epi-Pen. This product is an auto-injection device that can safely administer the correct dose to quickly counter allergic reactions such as bee stings. The drug initiates the body's fight or flight response, causing your heart rate to accelerate, your blood vessels to constrict and your airways to open which can be life-saving like in the event of anaphylaxis, where the individual's airways can swell and close. However, if not

used, the EpiPen has an expiration date of one year, at which time a new EpiPen must be purchased.

One testimony originates from the actress Sarah Jessica Parker whose son has a severe peanut allergy. The Belfast Telegraph reported:

*“I was recently involved in an initiative to raise awareness for anaphylaxis,” she writes. “It’s a cause deeply important to me because of my son’s life-threatening peanut allergy. . . I recently learned that the price of the EpiPen has been systematically raised by Mylan to a point that renders the medication cost-prohibitive for countless people.”*

The EpiPen was first developed in 1977, and purchased almost a decade ago by Mylan when the device was sold for \$57 each. In 2016, Mylan had increased the price to over \$500, a 400% increase. The competitors for this product and delivery system were limited with only one mentioned, Impax Laboratories’s, Adrenaclick product. The high price for the EpiPen was blamed on the auto injector and various middlemen. Mylan’s EpiPen profits, after they aggressively marketed this product, were \$1.2 billion in 2015. Bloomberg reported that EpiPen sales represented 40 percent of Mylan’s profits (Koons & Langreth, 2016). Consumer outrage was noted by the media and subsequently by Congress. Congress called for an investigation and requested CEO Bresch to testify. Senator Richard Blumenthal, Democrat of Connecticut, believed that a congressional investigation was warranted calling Mylan’s EpiPen, a virtual monopoly. While the defendant deflected criticism and focused on the future with Mylan’s new generic product in the works and patient -assistance improvements, lawmakers were in disbelief regarding Bresch’s testimony and the pricing scandal. The company had even lobbied for EpiPens to be required in schools, further expanding its reach. See Specialty Segment Operating Profit Margin (Appendix A). As a shareholder, though, the future looks bright, see (Appendix B)

In the absence of real competition, employers, insurance companies and benefits managers do not have any leverage to negotiate with Mylan. This issue is a greater concern in the pharmaceutical market with the growing costs of specialty drugs and the inability of many individuals who need the drug to pay for it. In 2017, specialty pharmacy expenditures are expected to continue to rise by another 16.8%, further contributing to the patient affordability crisis.

## **Executive Pay**

The company’s compensation plans exceeded most of the other comparable pharmaceutical firms with more employees, sales and research and development budgets. In 2011, the former CEO, Robert Coury’s pay package topped out at \$22.9 million rallying from \$8 million a few years earlier (Staton, 2016). The trend continued as media accounts have noted that the CEO Heather Bresch was one of the drug industry’s highest paid CEOs, with salary and stock of more than \$18.9 million in 2015. This was an increase of 671 percent from her 2007 pay of \$2.45 million (Popken, 2016). See the Executive Payroll chart (Appendix C).

According to the Mylan SEC Filing on 5-116, 2016, the company contends that their company’s executive compensation program is designed to create a maximum “return on executive leadership” and outstanding shareholder value. There was speculation that executive pay was tied to aggressive market targets potentially contributing to the Epicur breach at the top. The Wall Street Journal reported in September, 2016 that the EpiPen’s list price doubled, since the inception of the executive incentive plan in 2014. While the EpiPen prices were skyrocketing

at a whopping 400% increase and contributing 40% of the operating profits in 2014, executive pay was following suit with gains of up to 600% (Popken, 2016). Collectively, Mylan's senior leadership made over \$500 million in the last 5 years.

### **Relocation of Company**

Mylan's CEO, Bresch, complained that US tax laws create "an uneven playing field in our country. We really penalize U.S.-based companies" (Hiltzik, 2016). Mylan used a tax loophole to allow them to keep their offices in the US, but avoid US taxes on global income (they still pay US taxes on domestic income). They executed an inversion; this is a way for a US company to cut its tax bill by acquiring a foreign company and moving its tax domicile to that firm's home country. This was completed in 2014, when Mylan acquired a generics manufacturer from Abbott Laboratories and reincorporated in the Netherlands.

Inversions have been derided as unpatriotic by many, including former President Obama. It is ironic that Ms. Bresch was named a "Patriot of the Year" in 2011 by Esquire magazine for her work on the F.D.A. Safety and Innovation Act (Sorkin, 2014). Indeed, after the inversion, Mylan audaciously sought help from US antitrust officials to help prevent an unfriendly takeover from Teva, an Israeli company (which eventually fell through anyway). Teva though, did cite a cultural difference between the companies as they touted a pay-for performance mentality and fidelity to all of their stakeholders. It is noteworthy that the Los Angeles Times noted that Mylan's claim of an uneven playing field was not reality: Israel's top tax rate is 26.5 percent; the US top rate is 35 percent. Moreover, as true for many companies, Mylan was not paying the top US tax rate of 35 percent. Prior to the inversion Mylan's effective US tax rate was 16.2 percent in 2013, 20 percent in 2012, and 17.7 percent in 2011 (Hiltzik, 2016). Mylan's rate based on its Netherlands domicile was to be 21 percent in 2015, and in the high teens thereafter (Sorkin, 2014). Shareholders also received a shock when they were forced to pay additional taxes when the company moved their headquarters to Europe from Canonsburg, PA.

### **Mylan Board of Directors**

Mylan's Board of Directors have not been without controversy. Robert J. Coury, Mylan's current chairman who had served as chief executive until 2011, was stated to have used Mylan's corporate jet for personal use and to travel to his son's music concerts (Thomas, 2016). The Wall Street Journal notes that many companies allow executives personal use of employer's corporate jets. Mr. Coury does have a side business, however, he owns a record label Eleventh Records that promotes the music career of his son Tino Coury. Tino is a pop singer that had a Top 40 Hot Dance Club Song in his single "Diary" in May 2010 (Maremont & McGinty, 2012). In addition, the company also paid the taxes on the value of the aircraft usage, estimated at \$500,000 in 2011 (Staton, 2016).

The Wall Street Journal reported that Rodney Piatt, Vice Chairman of the Mylan Board, who served as lead independent director and compensation committee chair, was the lead developer on Mylan's new office building near Pittsburgh. Piatt allegedly sold the tract of land for \$1, a day before Mylan paid \$2.9 million in order to build their new headquarters on this site. Mylan had not publically disclosed this related party transaction (Maremont, 2015). They also did not disclose that a company with connections to Piatt was hired to oversee some of the construction too. Another similar transaction with Piatt and his business partner involved a \$9.2

million deal purchased by Mylan from the partner who had purchased the land from Piatt for \$10 (Staton, 2016). The Securities and Exchange Commission, subsequently investigated these land deals. The company denied that Mr. Piatt was involved in either of the transactions. Some outsiders have described Mylan's corporate governance as a weak point.

Family and political ties have also been in question. According to the Center for Responsive Politics, Mylan's political action committee has given substantial money to a variety of congressional candidates. Chief among them was Joe Manchin (Bresch's father) who has received \$122, 750, since joining the Senate in 2010. See the Top Ten Organizations Funding Joe Manchin chart (Appendix D).

## CASE DISCUSSION QUESTIONS

Use the case narrative, the charts and tables in the Appendix, and the references to answer the following questions:

List and describe some of the ethical issues in this case.

1. How do the price increases for the EpiPen reflect the Tone at the Top? Is the marketing and pricing strategy for EpiPens in congruence with Mylan's Code of Conduct and core values? Should companies charge what the market will bear?
2. Ms. Bresch's MBA from WVU was awarded under what appears to be false pretenses and subsequently revoked. Considering company HR policies and the tone at the top, what action(s) might be taken? Why?
3. What impact does the Board of Director have on the tone at the top? Should the Board of Directors have appointed Ms. Bresch CEO after this material was uncovered? What questions may have arisen? What reservations?
4. Bernie Sanders said that Mylan's greed is apparently limitless. "They didn't just raise the price of EpiPens, they also dodge U.S. taxes." Is Mylan practicing a double standard, when they charge US customers \$600 for an EpiPen while Mylan is trying to avoid US taxes? Why?
5. Some of Mylan's shareholders did not like Mylan's inversion to a Netherlands domicile. What is the role of the CEO and the Board of Directors in these decisions? What if their actions do not represent the shareholders' wishes?

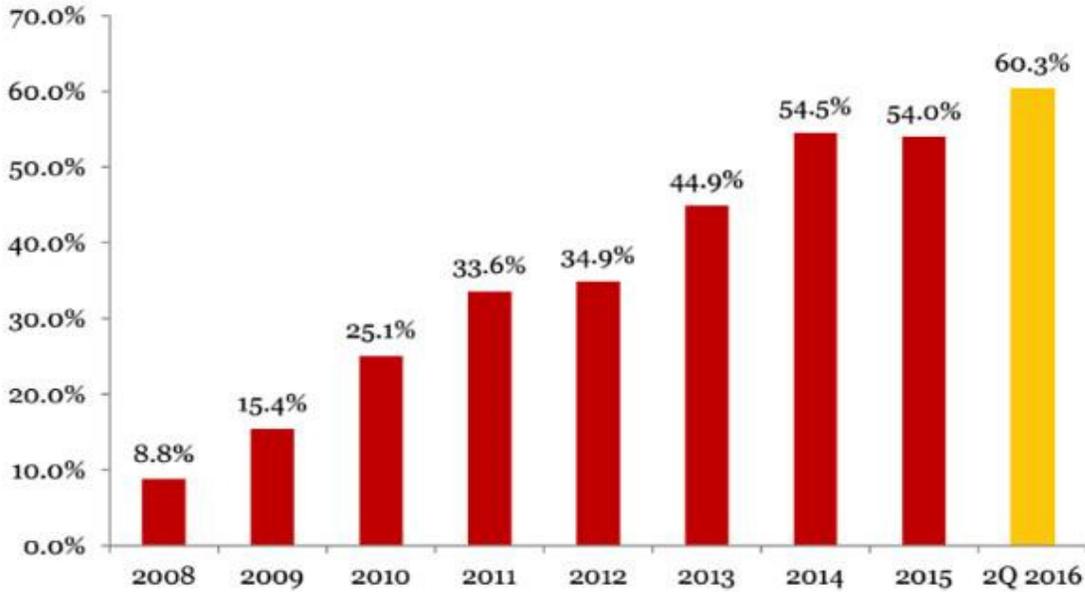
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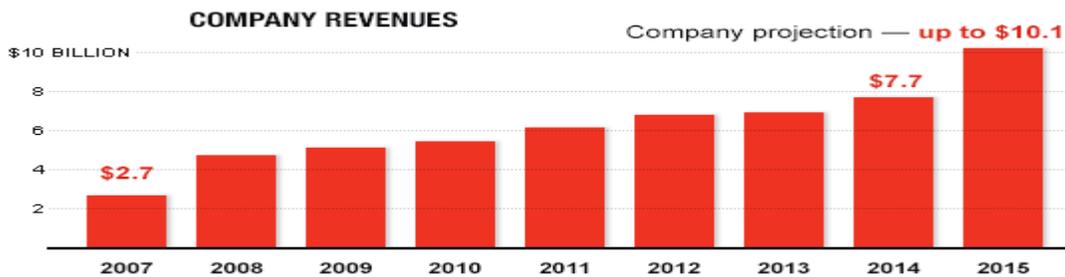
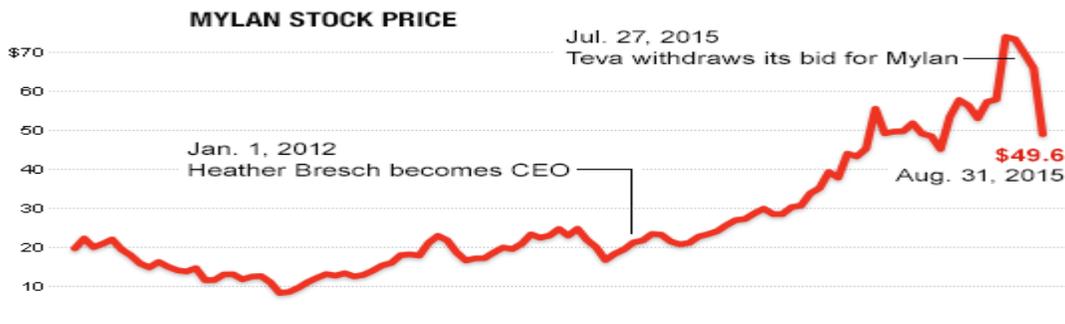
**APPENDIX A:**

**Exhibit 1. Specialty Segment Operating Profit Margin**



Source: Company reports and Wells Fargo Securities, LLC

**APPENDIX B: S&P Capital IQ: Mylan**



SOURCES: S&P CAPITAL IQ; MYLAN

**APPENDIX C:**

**Executive Payroll**

Top managers at Mylan had the second-highest pay of any U.S. drug or biotech firm over the last five years, even though Mylan is a relatively small player.



\*Total for 2011-15 †As of Sept. 7 Source: S&P Global Market Intelligence THE WALL STREET JOURNAL.

**APPENDIX D:**

**Top 10 Organizations Funding Joe Manchin III**

Organization	Contributions
Firstenergy Corporation	\$135,750
Mylan Incorporated	\$122,750
American Electric Power	\$64,450
Mepco Llc	\$64,400
Dominion Resources	\$63,400
Centene Corporation	\$55,900
Jackson Kelly Plc	\$54,575
Drummond Company	\$49,100
Boich Companies	\$49,000
Patriot Coal Corporation	\$48,400

Contributions above are for the last six years of available data, Jul 1, 2010 - Jun 30, 2016.