

Ethics Versus Economics: The EpiPen Scandal and the Role of the FDA

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Industry Analysis

Abstract: In this study, industry analysis is performed on the health care sector and pharmaceutical market, specifically on the auto-injector of epinephrine known as the EpiPen. In literature review, expert opinions on the economics and ethics of events that occurred surrounding the companies price gouging tactics are reviewed. How Mylan came about acquiring the monopoly and holding its grasp is also discussed. Data shows how the company's profits significantly increased every year while consumers struggled to pay the price out of pocket. Suggestions are made on potential ways to create more power for consumers in the market, as well as promote competition for suppliers.

INTRODUCTION

The EpiPen scandal in the United States of America is a fatal shortcoming of the health care industry. EpiPen treats Anaphylaxis, a life-threatening condition in which a person experiences an allergic response to a substance in their environment. Common causes of Anaphylaxis include foods, insect bites and stings, as well as medications (Peters). Many factors contribute to the rise in price for the life saving medication, including the fact the Mylan has a monopoly on the product. Mylan is a company owned by publicly traded Pfizer, one of the largest pharmaceutical companies in the world. The controversy began when the price of the drug, anaphylaxis, increased approximately 25% each year for over a decade. EpiPen was first purchased by Mylan in 2007, for 6.7 billion dollars from a company called Merck. At this point, a single EpiPen was sold for \$56.64 each. Mylan altered packaging, selling the product in pairs and raising prices up to 600 dollars for the two. As consumers continued to show a willingness to purchase the product, the costs continued to increase. Eventually, consumers began to refuse to purchase the product, preferring to take the risk of being without necessary life saving medicine rather than pay astronomical prices (Dorfman). The value created from high demand of the product is significant, but ethical issues behind the price hikes for these products must also be considered in health care.

LITERATURE REVIEW

Mylan is run by Chief Executive Officer Heather Bresch. The company was founded in 1961 with a mission statement reading “helping people in small West Virginia towns and rural communities gain access to affordable medicine” (Peters). Four decades later, in 2007, Mylan

had grown into a global firm going by a new mission statement reading “At Mylan, we are committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine” (Peters). The company also emphasizes innovation, reliability, leadership, and specifically “do what’s right, not what’s easy”. Following the purchase of EpiPen from Merck, the Mylan website read “At Mylan, we put people first, trusting that profits will follow” (Peters). All these messages are contradictory to the actions of price gouging performed by the company.

The Federal Drug Administration (FDA) has played its own role in the crisis. As of 2016 the only company in the United States selling EpiPens was Mylan, holding monopolistic power over the market. The FDA has rejected many companies who have tried to join the market. In comparison to the United States single producer of EpiPen, Europe has eight. Competition is extremely important, and if new companies do not compete with Mylan in the United States, then price gouging will continue to be a legitimate concern (Ho). One potential competitor was approved but the product was later recalled. Two other companies saw their bids to sell the product rejected by the FDA. The FDA is responsible for the safety of the public when it comes to drug administration, however, it should not be a challenge to develop delivery devices that the FDA can approve of. Forbes recommended if the government intended to increase competition in the market, waiving or increasing the speed of aspects of the FDA approval process would lower costs of entry and encourage companies to pursue the new markets (Dorfman). In “GOP E&C Members Ask if FDA Criteria to Blame in Part for EpiPen Mess”, according to lawmakers, laws and regulations “must promote a competitive prescription drug market” and “ultimately lower the cost of prescription drugs for America’s Patients” (Lim). Lawmakers asked questions of the FDA such as ‘how many applications for generic EpiPen’s have been submitted and how many

have failed'. They asked about pending applications and whether these applications are being prioritized. They even inquired about the approval criteria for such products (Lim).

The increase in prices due to Mylan's monopolistic position on the EpiPen market stirred much political debate. Politicians such as Chuck Grassley, a republican of Iowa, and Amy Klobuchar, a democrat of Minnesota, both pushed bills to prevent what is known as a 'pay-for-delay' (*Lim). This tactic was used to delay the appearance of Teva's generic EpiPen in 2011. Mylan filed a citizen's petition to challenge Teva's entry to the market just weeks prior to the deadline for the FDA's approval on the product (Lim). Klobuchar believes "this outrageous increase in the price of EpiPens is occurring at the same time that Mylan Pharmaceuticals is exploiting a monopoly market advantage that has fallen into its lap... Patients all over the U.S. rely on these products" (*Lim). An unnamed congressional staffer spoke with *Inside Health Policy* on a matter concerning Impax Laboratories Adrenaclik, a product explained as non-equivalent to EpiPen not being covered by insurance companies. The staffer says "Companies are finding ways of taking advantage of entry level barriers that aren't supposed to be there for competitive windfall... It seems like market failure, maybe it's the FDA, maybe not" (*Lim).

Mylan's Price Hike of EpiPens: Holding the Pharmaceutical Giant Accountable analyzes the need for the trade commission to investigate antitrust law violations in relation to anti-competitive and exclusionary contracts. The article also offers recommendations of how congress can approach the issue (Hadland). Mylan does not own a patent on the drug epinephrine but rather on the auto-injector of the EpiPen. The efficiency and convenience of the auto-injector also makes the Epi-Pen so valuable compared to tradition administration. Author Hannah Hadland broadly suggests the FDA should "allow more competing auto-injectors on the market" (Hadland). References for this include the FDA's recall on Auvi-Q auto-injector, sighting

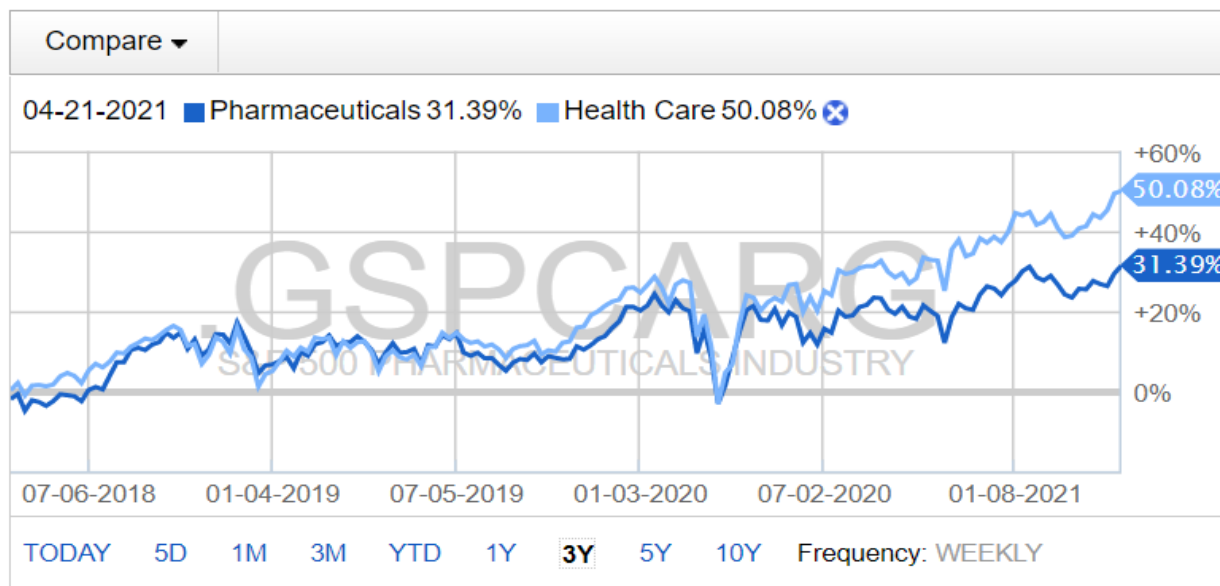
deficiencies in the delivery methods of the drug. According to the article, the number of times Auvi-Q auto-injector failed was about equal in ratio to the number of EpiPen failures, also mentioning many of the failures could be due to operator error. Hannah concludes that the FDA should allow more auto-injectors into the market as there is “no real fundamental differences” and then way things stand the FDA is only encouraging Mylan’s price gouging (Hadland). Lowering the standards for FDA acceptance on auto-injectors is a potential option. However, it may be even more beneficial to remove the prescription only requirement on the product, says Hannah.

Several politicians presented more alternative options to creating competition for Mylan Pharmaceuticals on the market. One group of bipartisan senators sought to explore if it would be justified to include a drug on the FDA’s drug shortage list due to price hikes. In turn, resulting in the FDA accelerating the approval process for more similar products on the market. In 2016, Hillary Clinton pledged to hold pharmaceutical companies responsible through funding research programs and requiring companies to justify their price tags. She called on Mylan to immediately reduce prices, as there was no justification for the current costs (Durkin).

INDUSTRY ANALYSIS

In the pharmaceutical industry, Pfizer is a leading company. They own a 53% stake in Mylan’s company, making Pfizer the majority owner. Pfizer operates in the pharmaceutical industry of the health care sector. The global health care industry represents approximately 10.3% share of spending in gross domestic product (GDP). A future increase in spending on health care can be expected due to factors such as aging population, technological advances,

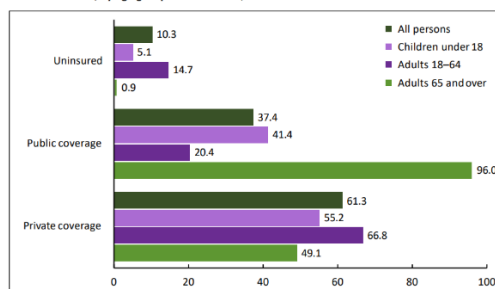
increase in demand, and expansion of public health care programs. The Coronavirus pandemic has been a driving force in health care innovations. Over the past five years, the health care sector represented approximately 13% to 15% of the United States stock market sector weighting and outperformed the S&P 500 index 9 of the previous 13 years. Prior to Coronavirus, the pharmaceutical industry saw slow growth. After the market collapse due to the pandemic in March 2020, the industry saw a quick recovery and helped drive the health care sector growth even higher than pre-pandemic levels (Fidelity).



Not only have we seen technological advances helping to reduce costs of care, increase efficiency to consumers, and increase profit margins but financial and regulatory barriers also have an opportunity to adapt to the new environment. A larger emphasis than ever before is being placed on preventative measures rather than treatment for these issues. The EpiPen is considered a preventative and due to the Affordable Care Act insurance companies are required to cover certain limits of preventative care. The Affordable Care Act also intends to extend health care coverage through affordability to as many American individuals and households as possible. However, with the EpiPen consumer struggles when required to pay large portions of

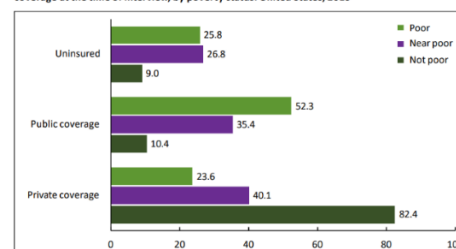
costs out of pocket. Preventative measure that are covered 100% by insurance companies includes hepatitis, human papillomavirus, and influenza shots and immunizations. Also included is STI-prevention, depression, alcoholism, obesity counseling, behavioral assessments and much more (Craford). However, the lifesaving drug epinephrine is not on this list and not all consumers have had success finding and affording health insurance. As of 2019, 10.3% of all people in the United States were uninsured. The largest age segment of this group being those 18 through 64, the working class. Income levels also influence insurance coverage. Those considered poor or near poor had a rate of approximately 26% completely uninsured (Cohen).

Figure 1. Percentages of persons who were uninsured or had public or private coverage at the time of interview, by age group: United States, 2019



Health Insurance Coverage: Early Release of Estimates From the National Health Interview Survey, 2019

Figure 4. Percentages of adults aged 18-64 who were uninsured or had public or private coverage at the time of interview, by poverty status: United States, 2019



According to Doctor Arthur Kornblit an allergic reaction can be “as mild as a sneeze or as severe as an anaphylaxis”, a life-threatening physical reaction in the immune system of a person experiencing an allergic reaction. Dr. Kornblit states there are on average 200,000 emergency room visits each year from serious food allergies. The average cost of EpiPen’s nationally is about 600 dollars (Kornblit). The number of EpiPen’s sold dropped approximately 300,000 units from 2015 to 2016. The idea that people were willing to risk being without the readily accessible and efficient EpiPen due to financial reasons is astonishing. While profitability continued to rise, consumers continued to struggle to afford protection. The sales numbers and profitability of EpiPen are as follows: (SEC.gov).

Following Mylan's recent testimony before the United States House of Representatives regarding EpiPen, Mylan is providing this analysis of the profitability in the United States of EpiPen as a supplement to its testimony. Mylan does not regularly provide profitability analyses for individual products and does not intend in the future to provide product level profitability analysis for EpiPen or to update this analysis.

(In USD millions)	2008	2009	2010	2011	2012	2013	2014	2015	2016E [3]
Sales	184	200	281	371	622	742	933	912	1,100
Cost of Goods Sold	79	86	123	139	195	202	224	255	275
Gross Profit	105	114	158	232	427	540	709	657	825
Gross Margin	57.1%	57.0%	56.2%	62.5%	68.6%	72.8%	76.0%	72.0%	75.0%
Operating Costs [1]	34	32	43	58	121	147	184	159	154
Operating Profit	71	82	115	174	306	393	525	498	671
Estimated Implied Interest [2]	67	66	65	62	56	42	24	-	-
Estimated Tax Impact	2	6	19	42	94	132	188	187	252
Tax Rate [4]	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%
Net Product Profitability	3	10	31	70	156	219	313	312	419

US Pens Sold (millions)	4.3	4.5	5.2	5.5	7.3	7.4	7.9	8.3	8.0
Approximate US Metrics per Pen (in dollars):									
Sales	43	44	54	67	85	100	118	110	137
Cost of Goods Sold	18	19	24	25	27	27	28	31	34
Gross Profit	24	25	30	42	58	73	90	79	103
Operating Cost	8	7	8	11	17	20	23	19	19
Operating Profit	17	18	22	32	42	53	66	60	83
Net Product Profitability	1	2	6	13	21	30	40	38	52

CONCLUSION

In 2018, Teva pharmaceutical was finally granted approval from the FDA on its generic EpiPen product in limited quantities. These generic pens now can be purchased anywhere from 300 to 400 dollars in comparison to the name brand 600 dollars. The generic price tag remains 600% higher than the \$50 price in 2007 (Kokosky). While not illegal for a company to get rich, price gouging tactics are unethical, and the government has the responsibility to make live saving medications readily accessible to those in need. Investors should consider the ethics of companies they invest in, rather than continue to enable malpractice. CEO of Mylan, Heather Bresch, continued to insist the company had increased availability of the product. She also claimed the company made important contributions to society through its awareness ad campaigns. In 2019 she stepped down from her position of CEO. However, the issues of the scandal and rise in profitability numbers continue and the issue speaks for itself. Adding competition to the market for EpiPens will eventually eliminate the ability to raise prices unethically, however, the FDA has made this extremely difficult prior to Teva's acceptance. The

FDA easing necessary acceptance requirements, investing in other pharmaceutical companies to ease the difficulty of entry, banning contracts such as pay-to-delay agreements, or simply declaring the drug as non-prescription all would benefit the consumers in this monopolistic market.

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