

Production of Adalimumab: A Humira® Biosimilar
(Technical Report)

A Virtue Ethics Analysis of Mylan's EpiPen Price
(STS Research Paper)

An Undergraduate Thesis Portfolio

Presented to the Faculty of the
School of Engineering and Applied Science
University of Virginia, Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science in Chemical Engineering

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May 1, 2022

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Socio-technical Synthesis: Biosimilars and Ethical Drug Pricing

Both my technical project and my STS project center around the high costs of pharmaceuticals in the United States, where I investigate how the burden of high prices on patients can be eased. In these projects, I explore the various factors of why prices are so high and discuss the workings of the pharmaceutical industry. However, these projects are different in the approach to preventing high drug prices. In my technical project, I focus on the design of a facility to manufacture a generic version of an expensive monoclonal antibody, attempting to improve accessibility to a life-changing medicine. My STS work instead focuses on a case of high drug pricing and explores the unethical behavior of the company which led to that result. Therefore, both of my projects can lead to a greater understanding of current issues and future improvements in pharmaceutical costs.

My technical work solves the problem of high drug prices by designing a process to manufacture a “biosimilar,” or a generic version of Humira (adalimumab). Humira is a type of drug called a monoclonal antibody (mAb) and can treat multiple chronic illnesses including Crohn’s disease, arthritis, and ulcerative colitis. However, it is extremely expensive for patients. As the patent for Humira is expiring in 2023, it is the perfect opportunity to introduce a generic version to the market. The design my team and I created lays out the plans for a continuous adalimumab manufacturing plant which includes specifications for all of the operations to be performed in the plant. In addition, our design utilizes single use materials as often as possible, which reduces the cost on the company and on patients as single use operations minimize the time and money required to clean and sterilize equipment. Our design will allow for a biosimilar to be created that can be sold for a lower price than Humira and in turn, drive down the cost of all adalimumab.

Through my STS research paper, I explore the ethical conduct of a pharmaceutical company in an attempt to explain what values lead companies to raising drug costs. The EpiPen is a type of epinephrine autoinjector (EPI) which patients who have severe allergic reactions are required to have on them at all times. When Mylan Pharmaceuticals purchased the EpiPen in 2007, it raised the price by 400%, which led to wide-spread outrage and criticism towards the company. My argument utilizes the theory of virtue ethics to claim that Mylan acted unethically because they failed to adhere to Michael Prichard's Virtues for Morally Responsible Engineers. By understanding Mylan's failure to follow good engineering values, we can better understand what actions lead to this type of price-gauging and prevent it in the future.

By working on these projects together, my experience and understanding was enhanced. My technical project allowed me to understand the design considerations that contribute to high drug prices and what choices can reduce manufacturing costs. Correspondingly, the STS research project allowed me to understand the ethical decisions and company choices that contribute to high costs. When working on both of these projects, I gained perspective on the whole pharmaceutical process including both manufacturing and marketing, which improved my ability to make technical decisions that will have a positive impact. Overall, working on both of these projects simultaneously allowed me to have a better understanding of how to ensure pharmaceuticals are affordable and accessible.