

Thesis Project Portfolio

Design of an Insulin Glargine Manufacturing Plant to Increase Affordability and Accessibility of Diabetes Medication in the Sub-Saharan Region of Africa]

(Technical Report)

From Bench to Market: A Multifaceted Examination of Insulin Pricing, Profit Margins, and Patient Advocacy

(STS Research Paper)

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Executive Summary

Despite being essential for the survival of millions worldwide, insulin, a hormone produced by the pancreas to regulate glucose levels in the body, remains unaffordable for many. Individuals with diabetes rely on insulin shots to compensate for dysfunctional insulin release and utilization, ensuring proper glucose control and storage. While advancements in insulin therapeutics aim to improve treatment and administration, the global prices of these vital medications remain prohibitively high. Notably, in the United States, the cost of insulin continues to escalate, despite its century-old production history. Accessibility of insulin in other economically disenfranchised parts of the globe remains an issue as well. This capstone portfolio comprises two projects which concern the production, distribution, and economics of insulin. The technical project involves the design of a manufacturing plant to produce and distribute insulin glargine, a long acting form of insulin, in Ethiopia to service the region of Sub-Saharan Africa. The STS paper involves exploring how pharmaceutical pricing strategies, profit margins, market dynamics, and political entities impact the affordability and accessibility of insulin for patients in developing countries by looking at different actors, regulations, and economics in the supply chain.

The technical project was completed over the course of a year by four chemical engineering students. The report designed an insulin glargine manufacturing facility capable of supplying insulin to six million individuals in Ethiopia. To achieve this goal of supporting a quarter of the diabetic population in Africa, the facility aims to produce three tonnes of insulin annually. The insulin is produced via recombinant expression from *E. Coli* in a fermentation cycle, before undergoing a series of transformation and purification steps. With an upstream and downstream process yielding an overall protein yield of 32.52%, each batch is projected to yield

approximately 10.28 kilograms of insulin. To meet the production target, the facility executes 272 batches per year, commencing and completing a batch every 28.5 hours. With a cost per unit of insulin set at \$0.05, compared to industry standard of \$0.2-\$0.3, the projected annual revenue for the facility stands at \$3.83 billion dollars. Through a discounted cash flow analysis, the project's economic viability has been established with an internal return rate of 60% at a discount rate of 20%.

By demonstrating the economic viability of large-scale insulin production, this project underscores the potential for solutions to improve healthcare access for diabetic populations in resource-limited settings. The substantial projected revenue indicates the potential for long-term financial sustainability. Although the proposed local manufacturing facility shows economic returns, the lack of accessibility in these regions means the reasons are beyond simple economic cost vs. profit considerations. The STS project provides clarification to what these reasons are by scrutinizing pharmaceutical pricing strategies, profit margins, market dynamics, and political influences. The study investigates the complex interplay between various actors within the insulin supply chain, using Actor Network Theory. These actors include pharmaceutical corporations like Eli Lilly and Novo Nordisk, insurance companies, pharmacy benefit managers, patient advocacy groups, and political regulations.

The project explains the consequences and outcomes of the relationships between these actors, including the practice of patent evergreening, which prolongs market exclusivity for pharmaceutical companies, thereby inhibiting generic competition and driving up prices. Additionally, the research explores the role of health insurance systems in exacerbating accessibility issues, particularly among marginalized communities based on race or gender. By tracing the interactions between pharmaceutical companies, regulatory bodies, and advocacy

groups, the study aims to make clear how decisions at each level impact insulin accessibility, from manufacturing to patient delivery.

The project offers insights into systemic barriers and opportunities for improving insulin access in developing countries through both a social and technical lens. The technical project describes how a local manufacturing process is possible, and economically feasible. The STS project outlines the external factors that contribute to the current economic and sociopolitical landscape of insulin as it affects patients. The portfolio as a whole provides a perspective on how exactly these issues can be remediated to allow people to receive the life saving medicine they need.