Thesis Portfolio

Developing EGFR-Targeted Nanoliposomal Therapeutics in Head and Neck Squamous Cell Carcinoma

(Technical Report)

The Impact of Biosimilars on the Provision of Value-Based Healthcare

(STS Research Paper)

An Undergraduate Thesis

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Sociotechnical Synthesis

One of the most pivotal issues at the center of inefficiency in the United States healthcare system is the lack of affordable care for the overwhelming majority of the nation. Both the STS research and the technical research projects addressed in this portfolio are linked to the issue of affordability in healthcare. The STS research specifically uses a socioeconomic method of analyzing a possible solution to lack of affordability and access, while the technical research involves developing a more cost-effective and efficacious drug therapy for Head and Neck Squamous Cell Carcinoma (HNSCC). In the biopharmaceutical industry, lack of affordability and access is even more rampant than in other sectors of the healthcare market. The technical work involves developing an alternative drug delivery mechanism which utilizes an existing FDA-approved biopharmaceutical drug for Head and Neck Squamous Cell Carcinoma (HNSCC). The technical research reflects how scientific investigation can be used to address the inefficiencies of this particular biopharmaceutical drug and potentially create a more medically effective and cost-efficient therapy using an existing drug. Alternatively, the STS research in this paper contributes an understanding of how healthcare markets operate and how the proposed solution of using biosimilar drugs as a catalyst for providing value-based healthcare may contribute to reducing inefficiencies and increasing access to the healthcare market. Holistically, the two research projects provide improved insight into the U.S. healthcare market and contribute perspectives from the drug R&D community as well as the general healthcare community.

The technical report found in this portfolio covers an investigation of developing a nanoliposomal drug delivery mechanism for FDA-approved biopharmaceutical drugs that have

been shown promising in clinical trials against HNSCC. The three drugs involved in the study were EGFR inhibitors named Erlotinib, Gefitinib, and Cetuximab. Erlotinib and Gefitinib are water soluble compounds that were shown to be promising against Non-Small-Cell Lung Carcinoma (NSCLC) and cancers in other isolated tissues while Cetuximab is a monoclonal antibody currently being tested in FDA-approved Phase-2 clinical trials with the use of the Ceramide Nanoliposome (CNL). The CNL is a liposomal delivery vehicle developed by the Kester Lab that contains its own unique lipid compound formulation and, along with ghost liposome formulations, comprises the group of delivery vehicles used in the study. The objective of the technical research project was to investigate various combinations of a single dissolved or bioconjugated drug with either a ghost liposome or a CNL and the effect these developed therapies had *in vivo* on human HNSCC cells and *in vivo* in a rodent model. The goals of the study were to identify which of these developed therapies proved to be most efficacious in treating HNSCC in laboratory and clinical settings as well as to model the stability of the therapies under *in vitro* conditions mimicking the human physiological environment. Ultimately, the idea is to use translational medicine for utilizing clinical trials results in perfecting a human-administered HNSCC drug delivery therapy.

The STS research investigates the relationship between the biopharmaceuticals industry and the healthcare market. More specifically, this paper analyzes how biosimilar products can influence the provision of healthcare in terms of quality and affordability of care. The paper aims to answer the question: *How can the use of biosimilars increase the affordability of healthcare and consequently shift the current healthcare provision model towards one that is value-based?* Value-based healthcare is assessed against the more widely-practiced volume-based care model

and is connected to the biopharmaceuticals market using literature review to collect research and evidence. The paper shapes this evidence into an argument by establishing the relationship between these value-based care and biosimilar products in healthcare. Actor-network theory (ANT) is utilized to assess how connections exist between biosimilars and the value-based care model and how key components and roles in both aspects allow physicians to practice using this model as opposed to the volume-based model. Scientific, political, and commercial aspects of these relationships and the network connecting the healthcare model and the drug markets are evaluated in this paper. The arguments made in this paper aim to establish that the introduction and use of biosimilars in the U.S. healthcare market, provide an economic advantage to both physicians and patients that allows the value-based model of healthcare to become the most efficient and predominantly utilized model of care provision. Through this research, a healthcare policy that results in more affordable and accessible healthcare in the United States can be investigated and developed.

Conducting these two research projects simultaneously provided a much deeper and clearer understanding of how the various hierarchies and moving parts operate within U.S. healthcare and clinical research. This understanding fostered a greater appreciation for various medical and healthcare communities including drug research and development, healthcare provision, and drug manufacturing. Obtaining perspectives from different areas and members of these communities proved to be a holistic learning experience and one that would not have been supported if only one of these projects was experienced. Additionally, valuable knowledge was gained concerning both the business and patient models and expectations. These experiences will positively impact and guide a successful future career embedded in engineering and medicine.

As a result, this research provides the groundwork for investigating and improving the biopharmaceutical and healthcare industries, both domestically and globally, for patients and providers.