Prospectus

Encapsulation of Dissociated Islet Cells for Type 1 Diabetes
(Technical Topic)

Utilizing Technological Politics to Examine the Mississippi State Lawsuit against Pharmaceutical Companies and Pharmacy Benefit Managers
(STS Topic)

By

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction and Socio-technical Problem:

In the 21st century medicine has been progressing at an unprecedented rate with innovations that have tremendously improved the standard of care. However, there are many marginalized populations that seldom benefit from this improved care because of an inequitable medical infrastructure and lack of standardized healthcare. I want to draw attention to the proposed solution: cost-efficient and translatable medicine. An example is to develop an alternative treatment for type 1 diabetes through islet cell transplantation. This alternative treatment can limit the need for daily injections of insulin and can create more effective and cost-efficient treatment for patients. Socially, it will promote accessibility to diabetes treatment for individuals of all levels of income and background.

Despite the promising success of this technical solution, there are factors within Science, Technology, and Society that need to be addressed. Firstly, the cost of scientific research for current medical innovation is tedious and expensive as it requires hundreds of lab hours and equipment. Technologically, there are costs associated with the technical development of the product and the financial compensation for the individuals developing the product. Socially, The United States is becoming increasingly unhealthy leading to an increased demand for economical health services (Krans, n.d.). However, this simultaneously creates a larger issue for consumers who may not have the financial means for these highly expensive medical treatments. Thus, this plight reveals the measures necessary to consider during the planning and development of this technology, which contains the ability to hurt marginalized groups and privilege others with regards to accessibility especially. To better illustrate this foreseeable problem, one must consider a related case to explore how a technological design affected power relations in a community. This will be examined within the framework of "Technological Politics" as a case

study of a lawsuit filed in Mississippi against various pharmaceutical companies and Pharmacy Benefit Managers (PBMs) to determine how the profit-oriented politics of these companies play a role in the intentionality of increasing prices of insulin.

Ultimately, we must simultaneously address the technical, social, and financial factors of medical care in order to promote accessibility and equity. Otherwise, millions of people will continue to not receive innovative healthcare due to socio-technical factors that were overlooked during the technology's developmental process. The technical project will depict the innovation of islet cell transplantation while taking into account social and economical barriers. The STS project will contrast this by examining the Mississippi Insulin lawsuit to illustrate the problems that arise when failing to take into account socio-technological factors of a technology.

Technical Problem:

Diabetes is a chronic disease that results in abnormally high levels of blood glucose after eating. In a healthy state, the body will store excess glucose through the release of insulin from pancreatic islet cells (Wilcox, 2005). The focus of this project, Type 1 Diabetes (T1D), is a chronic disease where the body produces insufficient to no insulin. T1D constitutes about 5%–10% of all cases of diabetes and nearly 64,000 individuals are diagnosed with T1D every year (*Statistics About Diabetes | ADA*, n.d.). T1D is an autoimmune disease, which means the individuals' immune system is specifically attacking the insulin-producing cells.

Early treatments for T1D primarily consisted of lifestyle changes such as tobacco, green vegetables, a carb-free diet, and fasting (Weatherspoon, 2020). This form of treatment lasted until the development of insulin medication in 1922 (Vecchio et al., 2018). As T1D is an autoimmune disease, these insulin medications need to be taken for life. Unfortunately, a common underlying concern is that insulin costs are incredibly high. Today, insulin can cost

individuals close to $1500 dollars a month (Tseng et al., 2020; Willner et al., 2020). With the average salary being close to $4,125 a month, it is evident that it is financially impractical for individuals to pay for life. Strangely, while the cost of producing insulin has gone down and the same materials are being utilized, the prices of common types of insulin have roughly tripled over the past decade. This is likely the result of pharmaceutical companies raising prices to maximize profits gained. This has resulted in one-fourth of diabetic patients no longer being able to afford their prescribed treatment plans (Hayes, n.d.). If pharmaceutical companies continue to increase insulin costs, it will result in diabetic patients resorting to rationing their supply or neglecting treatment altogether.

This leads to the need for a more equitable, cost-efficient, and sustainable T1D treatment that can restore endogenous insulin production within the body. Thus, the relevant research question is how to design a T1D treatment that can regulate blood glucose more effectively and economically than traditional insulin. Transplantation of donor islet cells is a promising treatment that can regulate endogenous insulin secretion (Srinivasan et al., 2007). However, the transplantation site has high levels of immune cell activity, which may result in significant transplant islet cell mortality. Hydrogel encapsulation is a promising method to protect islet cells from the immune system. The proposed solution is to utilize microporous annealed particle (MAP) gel. MAP gel is composed of highly concentrated hydrogel microspheres that are assembled in situ and covalently bonded to form a macroscale material with open-pore geometry (pores >10 μm) (Griffin et al., 2015). Dissociated islet cells can be encapsulated within individual MAP hydrogel microspheres using microfluidics, and the resulting porous scaffold allows for better integration with the body. Thus, the objective of this technical project is to design a microfluidic method to encapsulate and store islet cells within MAP gel to use for T1D

cell therapy. If successful, these encapsulated islet cells can be injected directly by the pancreas and over time, the islet cells will grow into the body and begin restoring insulin production. The evidence to analyze this design's value will be taken from studies measuring the viability of encapsulated dissociated islet cells following a freeze/thaw cycle, the functionality of the encapsulated islet cells within MAP gel, the encapsulation efficiency of the experimental setup, and the level of a foreign body response.

STS Research Problem:

Mississippi is a state plagued with Type 1 Diabetes with the most diagnosed cases in the entirety of America. Over 400,000 people in the state are living with diabetes. This represents 13.6% of the states' population (MSDH, n.d.). Local medical professionals and epidemiologists attribute some responsibility towards inadequate awareness of the disease, ease and accessibility to tasty but unhealthy foods, lack of resources, and high cost of treatment.

The current approach to address this increase in diabetes is through educating the population about living a healthy lifestyle and to start on treatments of insulin, which is a drug that effectively regulates the levels of blood glucose in the body. However, insulin costs are immensely expensive and continue to rise. Sources claim that prices have gone up by 1000% in the state (Jaglois, n.d.). In addition, the average monthly salary for parts of Mississippi with the highest levels of diabetes is $3,285 and monthly insulin treatments can cost up to $1,500 per month. As a result, insulin is inaccessible to many diabetic individuals and many have had to resort to rationing their insulin injections or forgo treatment. To combat this, the state spends $3.5 billion per year, which represents 1 in 4 health dollars spent (Hagen, n.d.). This has been met with little improvement. The inaccessibility of insulin treatments has led the state's Attorney General to file a lawsuit against Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express

Scripts, and OptumRx which are pharmaceutical companies and Pharmacy Benefit Managers (PBMs) that are responsible for producing and charging for insulin production (Anderson, n.d.). The lawsuit claims that pharmaceutical drugmakers are allegedly fixing prices of insulin by raising prices and refunding a substantial percentage of that price back through rebates to PBMs. Thus, the state is seeking $10,000 for each purchase of an at-issue diabetes medication (Anderson, n.d.). This demonstrates the complication that the benefits of insulin in society are limited by its inaccessibility to all diabetic patients. If we continue to consider insulin in purely functional terms, we will miss its effects on political power relations. Consequently, if society is informed of the effects that unreasonable costs of insulin treatments have on society, there can be greater efforts made to advocate for alternative treatments or regulation on pharmaceutical pricing.

I argue that insulin treatments, as a technology, shape power relations by privileging some and marginalizing others. Specifically, it is benefiting pharmaceutical companies and PBMs by giving complete control to decide the costs of all insulin treatments with minimum oversight from governmental or other regulatory agencies. This marginalizes those with inadequate education or financial resources, particularly diabetic residents of Mississippi, from accessing life-saving treatments. My research will draw on Langdon Winner's argument on technological politics where technological artifacts have political effects and the power to affect power relations. Applying this concept and framework, I will demonstrate that insulin acts as a political technology influenced by the politics of pharmaceutical companies and PBMs. These politics empowers large companies while neglecting the needs of diabetic patients. I will also elaborate upon Winner's concept of intentionality to further illustrate that such companies have intentionally increased the cost of insulin to maximize profit which comes at the expense of

diabetic individuals' health and welfare. This research will contribute towards the better understanding of the medical industrial complex as insulin and its producers are one of the main components. It will also emphasize the need for cost-efficient medicine and standardized healthcare. To undertake this analysis, I will utilize evidence from exclusive interviews with relevant parties, press and public reports of the lawsuit, and scientific articles discussing the history and practices regarding many of the involved companies.

Conclusion:

The deliverable of the technical project is encapsulated islet cells within MAP gel that can be transplanted into a diabetic patient to restore endogenous insulin secretion. These will serve as an alternative cost-efficient treatment to insulin injections. These encapsulated cells will also be capable of retaining functionality following a freeze and thaw cycle which will demonstrate its capability to be transported to different hospitals around the country. The STS research paper will strive to determine the relevant social factors and forces as to how and why pharmaceutical companies and PBMs have made insulin treatments inaccessible and inequitable by drastically raising prices. This will be accomplished with a thorough study of the framework of technological politics which will characterize how the politics of these profit-oriented companies manipulate the political technology of insulin to intentionally maximize profits and marginalize lower-income diabetic individuals. The combined results of this technical report will serve as a motivation to promote initiatives for islet cell transplantation and on a broader level, develop more cost-efficient medicine. Ultimately, the efforts of this study will pave the way towards a future of a more accessible and equitable standard of patient care.

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