

Therapeutic Patch

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Please note project is under NDA and as such specific details are omitted.

Project Motivation

- Drug currently offered as oral tablet or IV formulation
- Oral delivery causes blood level spikes and passes through the digestive system which causes unwanted physical symptoms

Project Goal

Improve patient quality of life through therapeutic patch that reduces organ rejection events by improving patient compliance and safety

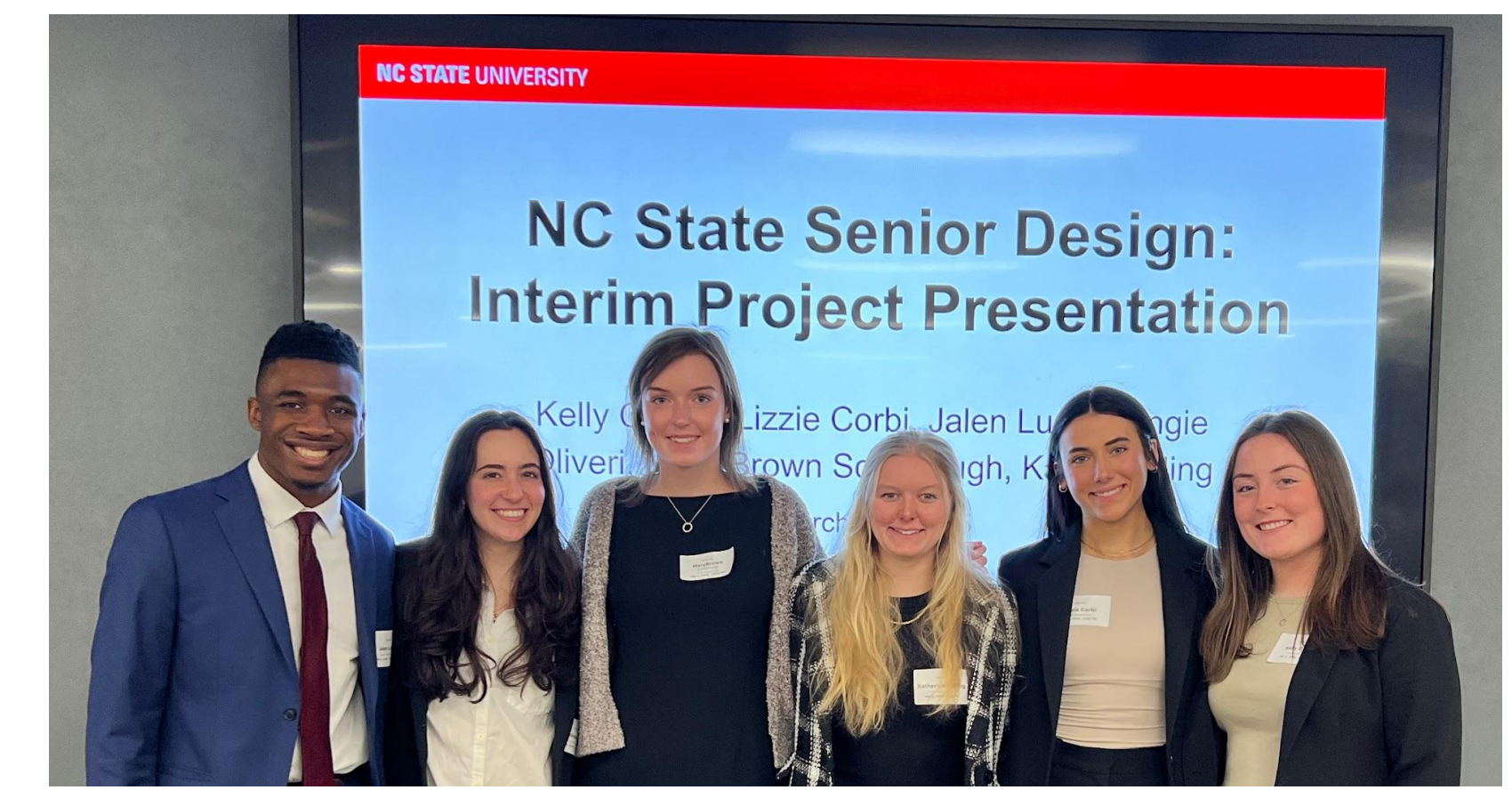
Project Overview

1. Patch Technologies
2. Manufacturing and Methodology
3. Formulation and Delivery
4. Manufacturing Plan
5. Economic Feasibility

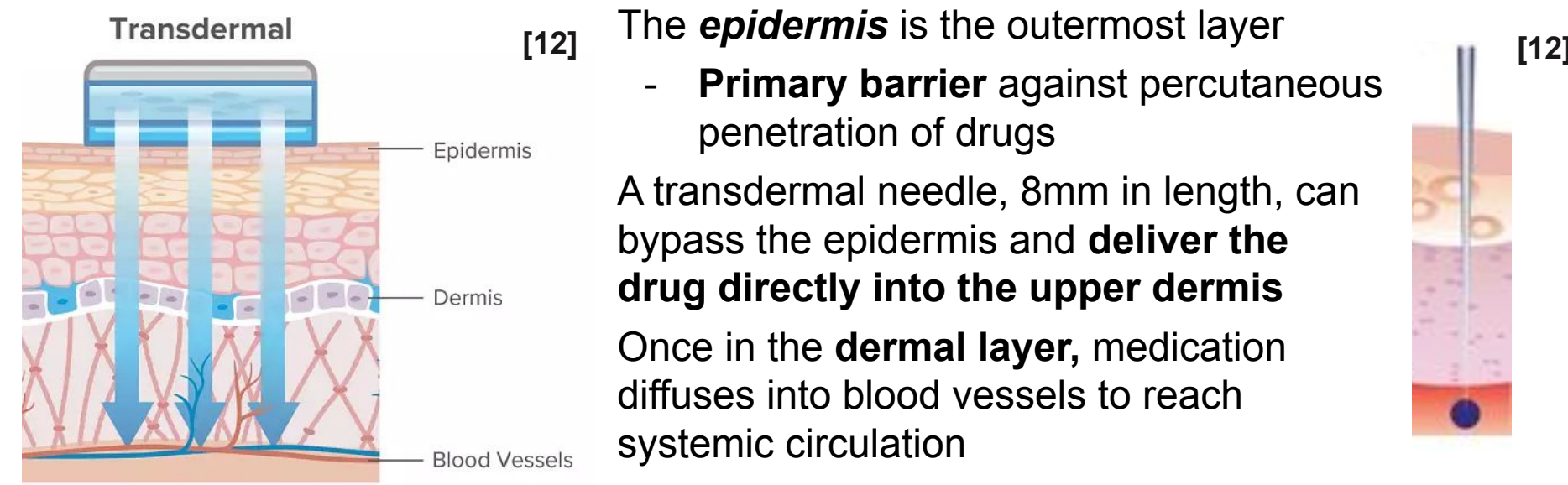
Economics

Raw Material Cost ~\$14.50
Market Price for Comparable Products ~ \$28.00 per unit
Estimated Profit Margin: 48.2%

With a production cost comparable to current market offerings and a potential profit margin of approximately 48%, the product demonstrates strong commercial viability.



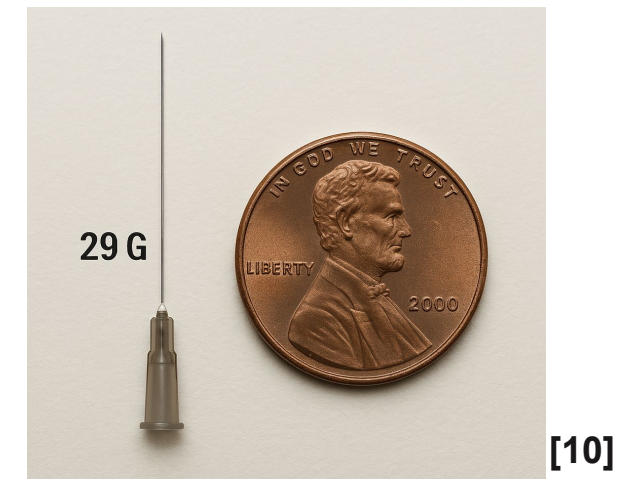
Transdermal Medication Delivery



A 29-gauge needle will achieve:

- Optimal balance of flexibility (anticipate patient activity in which device gets jostled)
- Patient comfort during device administration and wear

Stainless steel construction ensures biocompatibility, structural integrity, and reduced risk of breakage during use. Despite its small size, the needle maintains sufficient internal diameter to support laminar flow of the drug, ensuring consistent and efficient delivery.

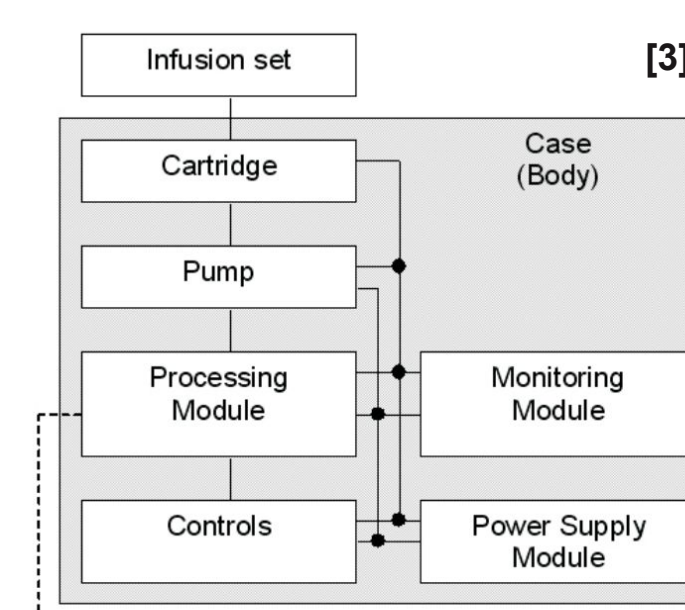


Medication Pathway and Transport Theory

1. Drug stored in reservoir
 - Insulate from the heat of body to prevent drug breakdown
2. Pump from reservoir out through needle
 - Transport Theory for basis: Hagen Equation
 - Volumetric flow rate of laminar flow through circular tube:

$$Q = [\pi(P_0 - P_L) R^4] / (8\mu L)$$
 - L: 8 mm (needle length)
 - R: 0.092 mm (needle radius)
 - μ : viscosity (TBD from suspension strategy)
 - $P_0 - P_L$: pressure difference/resistance (TBD pump piston)
3. Diffusion through dermis to nearest capillary
 - Unknown data for medication thus determined via porcine skin model
4. Capillary to systemic blood circulation
 - Known data from established IV administration route
5. Passive diffusion into cells to bind to the target receptor
 - Known data from established IV administration route

Tubeless Patch Design

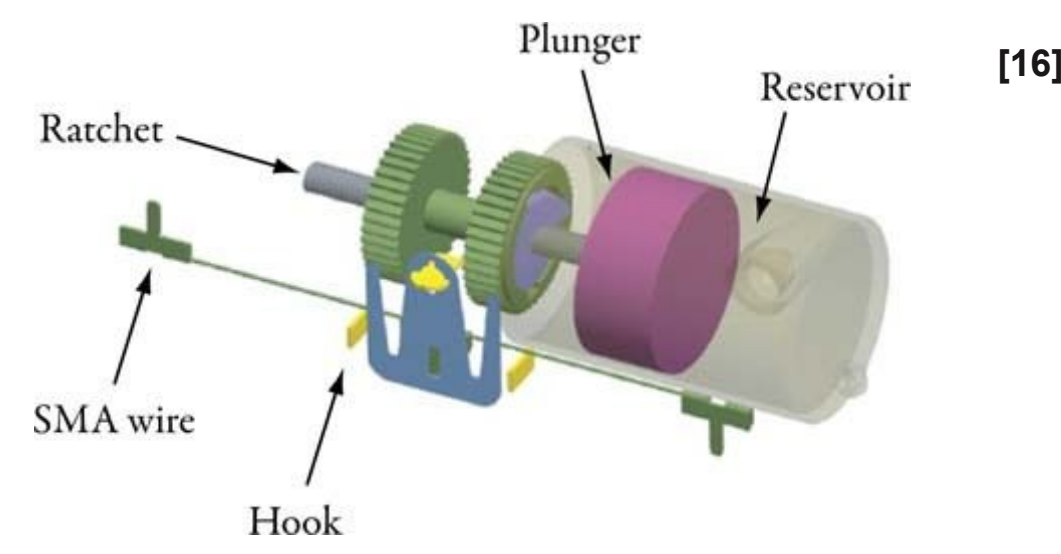


Materials of Construction

- Polyethylene:** Durable and collision-resistant
- Stainless Steel:** Corrosion resistant and biocompatible
- Acrylic Adhesive:** Hypoallergenic and extended wear
- Rubber Polymer:** Chemically resistant



Patch Mechanism



Shape Memory Alloy (SMA) Wire Technology

SMA wire alternates between expansion and contraction, driving gear rotation and piston motion to precisely inject the drug

Two Step Process: Piezoelectric Actuation and Piston Pumping

Piezoelectric actuation forces generate a mechanical strain, driving piston motion to effectively overcome fluid resistance

Suspension Strategies

Suspension Strategy:

- Basis: Solu-Medrol as a Model
- Shipped as a sterile powder, reconstituted into a suspension before administration
- Delivered intravenous or intramuscular routes, closely resembling transdermal infusion
- Suspension Medium: Bacteriostatic Water
- Composition: Sterile water with 0.9% benzyl alcohol



Alternative Strategy:

- Adoption of Intravenous Formulation
- Composition (per 1mL):
 - 5mg equivalent anhydrous drug
 - 200mg polyoxyl 60 hydrogenated castor oil
 - 80% v/v dehydrated alcohol
- Administration:
 - Diluted with 0.9% Sodium Chloride Injection or 5% Dextrose Injection



Dosing

Dosing Control Mechanism

- Ensure uniform volume delivery with each pump activation cycle
- Adjust dosing by modulating pump activation frequency throughout the day
- Optimize drug concentration by varying levels in the reservoir solution

IV to Oral Conversion Assumption: 1 mg/kg/day IV \rightarrow 7.4 mg/kg/day oral

Pump Activation Frequency: 1 per hour, expels 0.01 mL of fluid

Reservoir Capacity: 3.2 mL of reconstituted fluid

Oral Dose per Day	Transdermal Infusion Dose per Day	Transdermal Infusion Dose per Week	Pump Activations per Week	Volume Expelled per Week by Pump	Concentration of Drug in Reservoir
0.5 mg	0.07 mg	0.490 mg	168.0	1.68 mL	0.292 mg/mL
2.0 mg	0.28 mg	1.96 mg	168.0	1.68 mL	1.167 mg/mL
6.0 mg	0.86 mg	6.020 mg	168.0	1.68 mL	3.583 mg/mL

Minimum Dose (.07 mg/day), patch can last 13 days as limited by dilution
 Maximum Dose (25 mg/day), patch can last 8 days as limited by precipitation

Insurance

Average Cost of on Market Comparable Pump Monthly:

- Without Insurance
 - \$259.75
- With Insurance
 - \$47.00-\$127.28

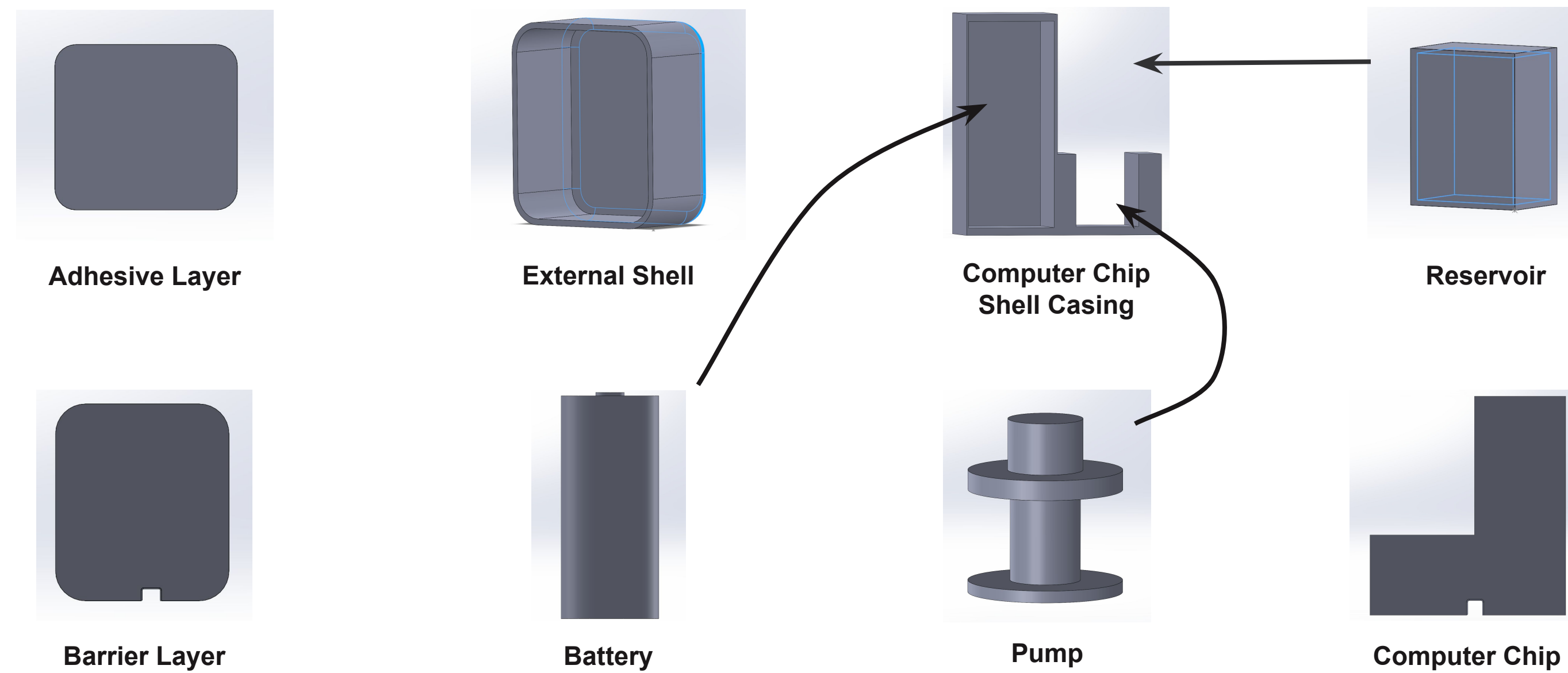
Average Cost of on Market Comparable Drug: 6mg concentration Monthly

- Without Insurance
 - \$1251.30
- With Insurance
 - \$299.97-\$613.18

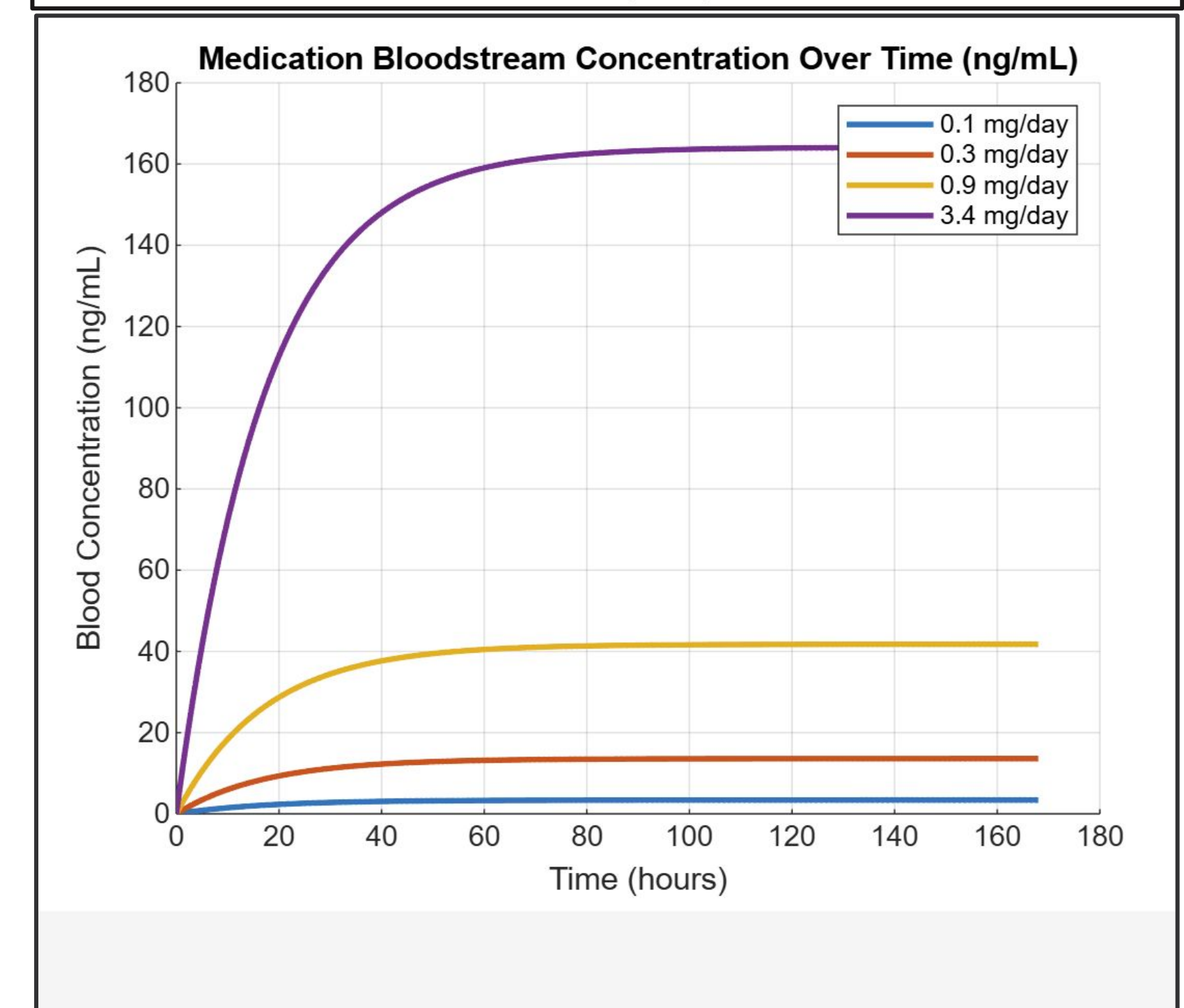
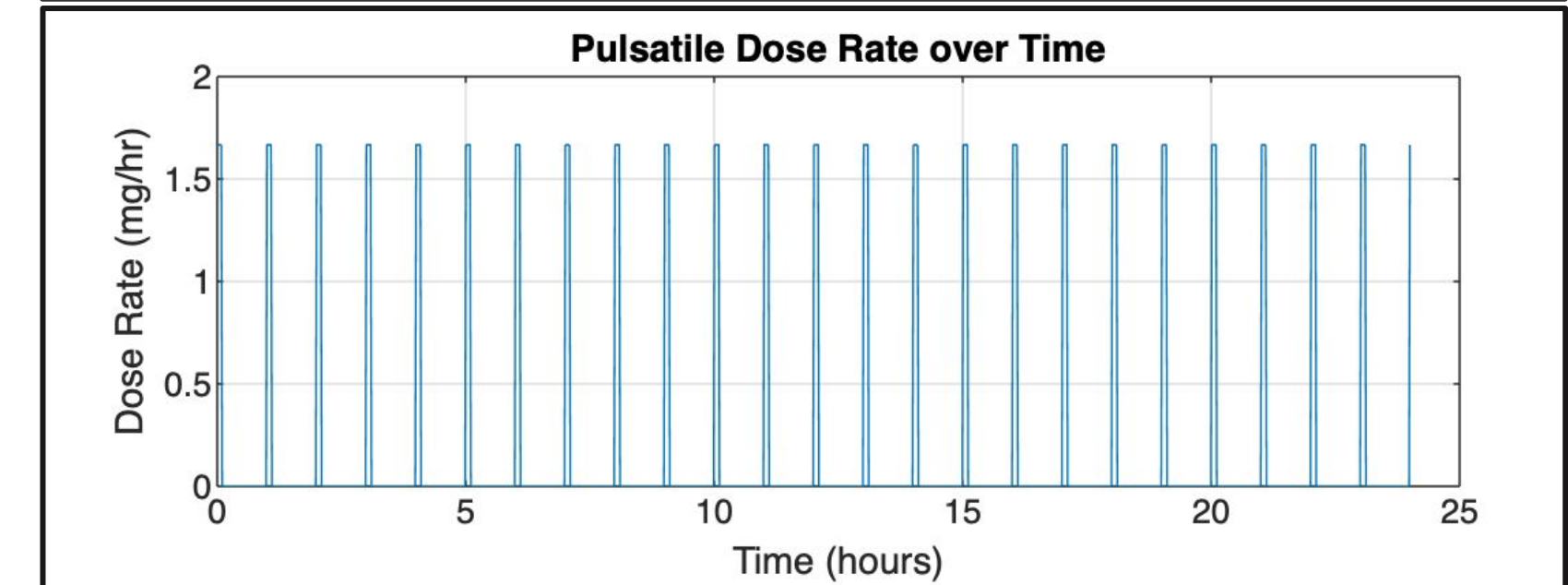
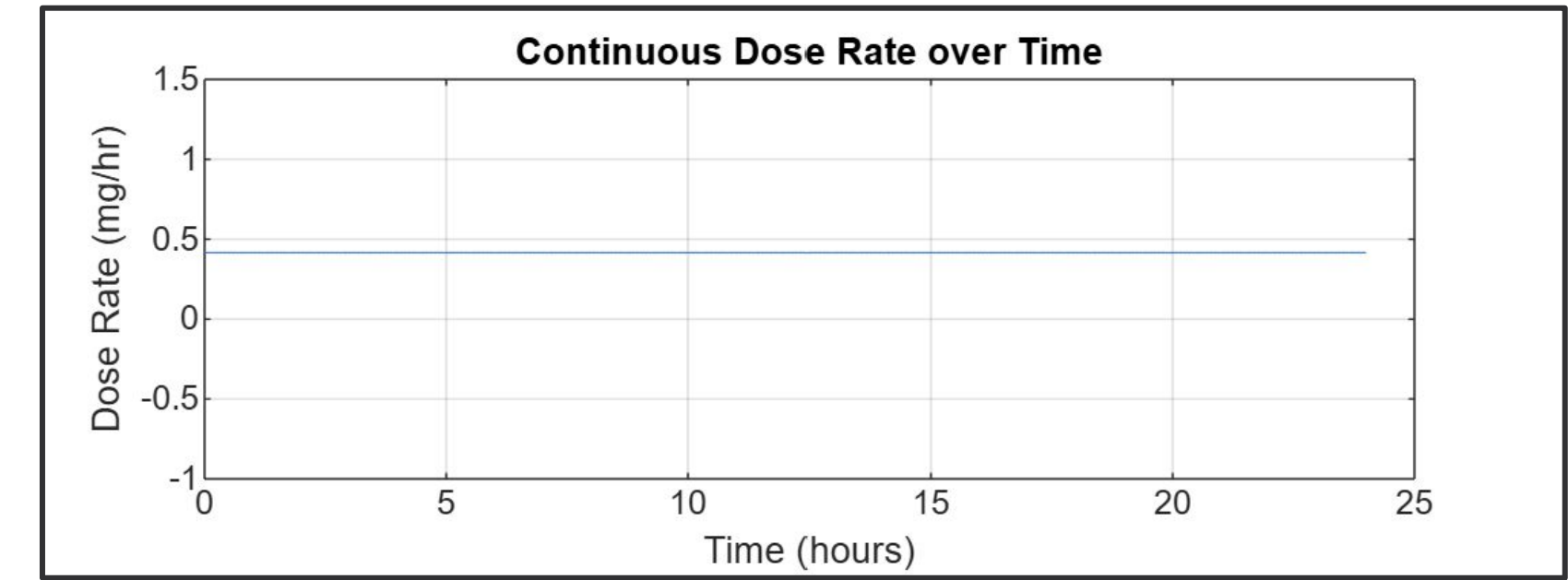
Average Cost of Drug and Pump for a Year Supply

- Without Insurance
 - \$118132.60
- With Insurance
 - \$4163.64-\$8885.47

Manufacturing



MATLAB



Graph 1: Shows what the dose rate would look like if it was continuously delivered into the body
Graph 2: This is how the pump will really work. One "pulse" or piston pump per hour (showed on a 24 hour scale)
Graph 3: (in reference to Dosing) the blood concentration of the medication over the course of wear of the patch (7 days= 168 hours)

Resources

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