Modified Inhaler Adapters
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Introduction

Motivation:
● 30,000 people have asthma attacks and 5,000 individuals are hospitalized every day.
● The combination of a small surface area and lack of force distribution on the traditional top-down push design makes it difficult for children, elderly, and individuals with neuromuscular diseases to self-administer a dose of asthma medication.

Cost of Product

<table>
<thead>
<tr>
<th>Adapter</th>
<th>Manufacturing Cost (per unit)</th>
<th>Selling Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Area Adapter</td>
<td>$7</td>
<td>$17</td>
</tr>
<tr>
<td>Squeeze Adapter</td>
<td>$10</td>
<td></td>
</tr>
</tbody>
</table>


Potential Market and Impact

Product Users
● People who require assistance using an asthma inhaler
● People who suffer from neuromuscular disease, elderly over age 65, children under age 12

Market Size
● 105 million people in U.S. have neuromuscular disease are over age 65 and/or are under age 12
● ~8% of population has asthma

Results in a potential market of 8.5 million in U.S.

Distribution
● Distribution through pharmacies and medical practices

Competitors
● Aerogen Solo
  (+) more effective drug delivery
  (-) bulkier, more costly
● Dry Powder Inhalers (alternative product)
  (+) better update of medication by patient
  (-) more costly
  (+/-) dispenses different types of medication

Inhaler Adapters

Area Adapter
Designed to increase surface area for users to apply medication with ease

- Users push down on the three tabs similar to current inhalers
- By increasing the surface area, less force is required
- Size of inhaler is increased by 20% with the adapter

Squeeze Adapter
Allows users to squeeze instead of push down to operate

- The squeeze mechanism redirects the force exerted from lateral into a vertical direction
- Each adapter uses the entire hand rather than a single (or multiple) finger(s)
- Size of inhaler is increased by 65% with the adapter

Testing and Results

Standard Inhaler
- Average Force Exerted for the Thumb and Finger for a Traditional Inhaler

Area Adapter
- Requires 7.6 pounds of force
- Average Force Exerted per Finger for the Area Adapter

- Requires 8.2 pounds of combined finger force showing 10% design inefficiency
- Decrease in at least 48% force per finger

Squeeze Adapter
- Requires 9.4 pounds of combined finger force showing 25% design inefficiency
- Decrease in at least 45% force per finger

Anticipated Regulatory Pathway

- Inhalers are classified as ear, nose and throat drug administration devices, which are housed under the Office of Device Evaluation
- According to the FDA, inhaler adapters are Class I devices
  ○ Low-risk device
  ○ 510(K) is not required; need proof of safety and effectiveness
  ○ Premarket notification application and FDA clearance not required
- According to FDA, inhaler adapter has manufacturing and marketing requirements:
  ○ Proper listing and labeling
  ○ GMP not required

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References