ThinAir: A One-Time Use, Ultrathin Rescue Asthma Inhaler

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Executive Summary

The objective of this project is to solve the problem of low patient compliance of asthma rescue inhalers. This low patient compliance results in over 2 million hospital visits a year. We have attributed the low patient compliance to the inconvenience to carry around the large, bulky device that is the current inhaler. The motivation of this project stemmed from the observations of one of the group members who is a life-long asthma sufferer. To solve this problem we have developed a prototype over the last year which is small enough to fit anywhere you go. This device, which is smaller than a credit card and only 1 mm thick can fit anywhere from a wallet to a jacket pocket, and due to its flexible nature, can also fit in a runner’s wristband. By predispersing the medication onto a cloth, we eliminate the need for the bulky dispersion mechanism thus, making this a fully portable device.

Clinical Need

• 34.1 million asthma sufferers
• Only 19.5 million use rescue inhalers
• Patients often do not carry their inhalers due to their bulky size
• Low compliance results in large amount of emergency room visits (25% of all emergency room visits in the United States)

Market Analysis and Reimbursement

• 34.1 million asthma sufferers
• Majority of asthma sufferers use pressurized aerosol albuterol inhalers
• Thin Air does not suffer from the bulkiness of rescue inhalers, giving it a definitive competitive advantage over tradition inhalers
• ThinAir is a similar device to our and is currently in the patent stage
• Our device is thinner, more portable, and is disposable, offering distinct advantages over this device
• Our Device Falls under the HCPCS code for the unit dose form of albuterol
  • We would be reimbursed at a rate of $0.47/mg
  • 20 doses/box * 50mg/dose * 8.3%albuterol *$0.47/mg = $40/box

Description of Design

Our design is split up into four primary parts. The base, straps, and sliding door are all made out of a material called Polyethylene Terephthalate Glycol-modified (PETG). We picked the material based off of its physical and chemical properties. The different PETG parts are melded together using Methylene chloride.

The Base:
• Provides the user with surface to grip
• Provides the structural foundation for the other PETG parts as well as the cloth
• Designed to be flexible and portable due to material elasticity and physical size

The Straps:
• Holds the sliding door in place
• Keeps the sliding door moving only in 1 degree of freedom

The Sliding Door:
• Provides the user the ability to unlock the hole and cloth underneath
• Lip provides extra grip for the user to pull out
• Arrows are etched in to show the direction of the required pull
• Prevents albuterol powder from dispersing around (both within the container and when it is opened)

Cloth:
• Cellulose cloth filter is used to house the pre-dispersed albuterol powder
• Prevents powder from clumping and/or escaping
• Allows air to flow through the backside in order to propel medication into user’s mouth

Novelty

Current Rescue Inhalers
• Require mechanisms to disperse medicine
  • Pressure
  • Directed inhalation
• Mechanisms for dispersal are often bulky and lead to inconvenient devices

ThinAir
• Medication is predispersed
• No additional mechanism is required for dispersal
• Thin, flat form factor can be achieved

Estimation of Product Costs

<table>
<thead>
<tr>
<th>Part</th>
<th>Amount/Unit</th>
<th>Bulk Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plastic Device</td>
<td>1 part</td>
<td>$120.00/1000 pieces</td>
</tr>
<tr>
<td>Microfiber/cellulose cloth</td>
<td>12.25 square cm</td>
<td>$10.09/10000 square cm</td>
</tr>
<tr>
<td>Albuterol</td>
<td>10 mg</td>
<td>$50/100000 mg</td>
</tr>
<tr>
<td>Mylar Packaging</td>
<td>42 cm square</td>
<td>$9.94/25084 square cm</td>
</tr>
<tr>
<td>Total Cost Per Unit</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Pathway

• ThinAir is a Class II device with similar devices on the market already so a $10(k) is appropriate
• Since we use albuterol sulfate, like the majority of other rescue inhalers and the only difference is our method of dispersion, we only have to prove that our method works using the methods set out by the United States Pharmacopeia,

Future Work

• Study user interaction and response
• Optimize packaging
• Get FDA Approval and Medicare and market device

References

2 Optimize packaging method works using the methods set out by the United States Pharmacopeia, since we use albuterol sulfate, like the majority of other rescue inhalers and the only difference is our method of dispersion, we only have to prove that our method works using the methods set out by the United States Pharmacopeia.
3 Based on the description of the device and related information, the device is a Class II medical device. A Class II medical device is one for which the manufacturer must demonstrate that the device is safe and effective. This is typically done through pre-market notification (510(k)) or pre-market approval (PMA). For more information on the classification of medical devices, see <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/DeviceRegulation/default.htm#regulation>.