Standardization of a Puff from Electronic Nicotine Delivery Systems (ENDS)

The Crown JUULs of ENDS

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Acknowledgements: Dr. Richard Dalby & Dr. James Polli
Invented in 1965 by Herbert Gilbert

Since 2003 the technology has evolved to 5 generations

Over 500 brands of e-cigarettes

37.3 % of high school seniors reported to using e-cigarettes in the past 12 months (NIDA)
Current Federal Regulations

Child Nicotine Poison Prevention Act of 2015

FDA’s Tobacco Rule: extending FDA’s regulatory power to include e-cigarettes as tobacco products in 2016

Stopping Appealing Flavors in E-Cigarettes for Kids Act – Current Bill

Marketing order required for new tobacco products
  Substantial equivalence (SE) for new tobacco products under FD&C Act
First Generation Electronic Nicotine Delivery Systems (ENDS)

- **Mouthpiece:** User inhales from this end.
- **Sensor:** Detects when user puffs.
- **Battery:** Power source that draws power from USB port.
- **LED:** Illuminates when in use, simulating cigarette glow.
- **Cartridge or Pod:** Stores liquid solution of glycerol, flavoring and nicotine.
- **Atomizer:** Heats the liquid, creating vapor, when user inhales.
- **Microprocessor:** Controls atomizer and LED that glows when in use.
JUUL Rises as Cigarettes Fall

Average JUUL Percent of Market Share* by Volume

Average Percent Y/Y Change in Monthly Cigarette Pack Volumes

Source: Nielsen & IR
*Total market calculated as cigarette packs and JUUL pods sold

The rate of decline in consecutive months has surpassed anything the tobacco industry has experienced in 5 years.
FDA Priority Areas

**Priority Area 1:**
Modernize Toxicology to Enhance Product Safety

**Priority Area 4:**
Ensure FDA Readiness to Evaluate Innovative Emerging Technologies, Strategic Plan for Regulatory Science

**Priority Area 8:**
Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products: Strategic Plan for Regulatory Science
Lack of Standardization of Puff Profiles in Literature

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Puff duration (seconds)</th>
<th>Inter-puff Interval (seconds)</th>
<th>Volume (mL)</th>
<th>Flow Rate</th>
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<tr>
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Variability in Yield by Puffing Profile

Variability in Yield by Puffing Profile

Nicotine yields from 15 puffs varied by more than $50$-fold across conditions.

Why define a puff for a *first generation* product?

Lack of standardization among current literature

  Allows for comparison of experiments

  Sets the standard for regulation of future generations

Improves comparison between products for premarket tobacco approval and substantial equivalence

Gives a guideline for the measure of exposure
## Literature Review of Puff Topography

<table>
<thead>
<tr>
<th>Reference</th>
<th>Subjects</th>
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<th>Flow Rate (mL/sec)</th>
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<td></td>
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<td><strong>Weighted Average</strong></td>
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<td>2.57</td>
<td>27.51</td>
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Proposed Standard Puff Definition for First Generation Products

<table>
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<tr>
<th>Puff Duration</th>
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<tbody>
<tr>
<td>Inter-Puff Interval</td>
<td>30 seconds</td>
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<tr>
<td>Volume</td>
<td>75 mL</td>
</tr>
<tr>
<td>Air Flow Rate</td>
<td>30 mL/sec</td>
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</tbody>
</table>

Voltage to be matched to that of the stock battery
Implementation

Guidance documentation to researchers and industry detailing standard puff

A standard puff would allow the FDA to stay better informed and well-equipped to evaluate all first generation e-cigarettes

Suggesting that FDA-sponsored studies utilize the puff standard definition

Inter-institutional cross-talk
## CORESTA vs UMB Puff Definitions

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<th>UMB</th>
<th>CORESTA</th>
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<td>55 mL</td>
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<tr>
<td><strong>Air Flow Rate</strong></td>
<td>30 mL/sec</td>
<td>18 mL/sec</td>
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**Advantages of the UMB puff definition:**
- Study citing average user air flow rates: 20-39 mL/sec
- Focus on first generation e-cigarette products
- Definition based on literature
We propose a standardized puff definition to:

- Characterize HPHCs
- To have comparable scientific literature
- As a gateway to regulate the newer generation of products

Our proposal would improve methods to convey complex scientific and quantitative information about product risk and benefits to consumers and professionals
References

FDA Resources

Images (in order of appearance):
http://www.jrsmarcom.com/content-is-king/crown
https://patents.google.com/patent/US3200819
https://www.coloradohealthinstitute.org/sites/default/files/download_files/Figure1.jpg
https://brands普京.com/2019/01/07/cigarette-decline-rates-accelerate-as-juul-share-grows
https://www.vaporfi.com/blog/wp-content/uploads/2015/01/Chalice_Setup24-1.jpg
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Cunningham et al. (2016). Development, validation and application of a device to measure e-cigarette users’ puffing topography. Scientific reports, 6, 35071.
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