Perceptions and Perspectives of ENDS Regulation of Vape Shop Operators in the Southeastern United States, 2015.

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### Background

**Introduction/Background:**
- Use of electronic nicotine delivery systems (ENDS) has increased dramatically in the U.S. in recent years.
- Refillable tank systems known as “vapes” (including devices, components and liquids) dominate this market and are primarily sold in specialty vape shops.
- The U.S. has over 8500 vape shops.
- Proposed FDA regulations of ENDS are currently under review.
- State and local jurisdictions have enacted local controls.
- Knowledge of vape shop operators’ ENDS regulation-related information, perceptions, and perspectives has not been previously studied.

**Federal Regulations:**
- Some described specific federal regulations of ENDS.
  - “…local governments have acted to regulate the sale to minors. They’ve acted, activated legislature to keep e-cigarettes out of certain areas, you know, public buildings, government buildings, et cetera.”

**State or Local Regulations:**
- Most described specific ways in which the sale and/or use of ENDS products were being regulated by local jurisdictions.
  - “…everything that is in the juice is already FDA approved.”
  - “I will say that the regulated devices definitely give you a good wealth of information.”

Most stated that ENDS are not federally regulated.
- “…there is no approved regulation at this point and time, so we are all basically self-regulating.”
- “I know that it’s in progress to be.”

### Objective & Methods

**Objective:** To assess vape shop operators’ knowledge, perceptions, and perspectives of current and potential future regulation of ENDS in general, and specifically at the point of sale.

**Methods:**
- Five cities were randomly selected within four Southeastern U.S. states (FL, GA, NC, SC).
- Vape shops were identified through Internet searches; five operators were recruited from each of the four states.
- Being an owner or manager of the shop, over 18 years of age, and able to converse in English were inclusion criteria.
- Following informed consent, semi-structured telephone interviews were conducted using a qualitative approach.
- Participants were compensated for the 20-30 minute telephone interview with a $50 gift card.

### Analysis

**Qualitative Analytical Approach**
- Transcripts of all recorded interviews were analyzed using NVivo® qualitative data analysis software.
- Codes were developed by the authors.
- Relevant codes were compiled into a master list and entered into the software with explanatory definitions to assist in the coding.
- A master list was designed with these identified codes; it was developed and refined iteratively as emergent themes were identified.
- Inter-rater reliability was assessed and discrepancies were resolve by authors’ consensus.

### Results - Knowledge of Current Regulation

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### Results - Perspectives of FDA Regulation

<table>
<thead>
<tr>
<th>FDA Regulation Support</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-juice safety &amp; quality control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age restrictions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General</td>
<td></td>
<td></td>
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<tr>
<td>Device safety</td>
<td></td>
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<tr>
<td>Point-of-sale location</td>
<td></td>
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<tr>
<td>Taxes</td>
<td></td>
<td></td>
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<tr>
<td>Where product can be used</td>
<td></td>
<td></td>
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<tr>
<td>Flavors</td>
<td></td>
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<tr>
<td>Self-regulating</td>
<td></td>
<td></td>
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<tr>
<td>Not as a tobacco product</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taxes</td>
<td></td>
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</tr>
<tr>
<td>General</td>
<td></td>
<td></td>
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<tr>
<td>Safe product</td>
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</tbody>
</table>

**Likely Impact FDA Regulation**

<table>
<thead>
<tr>
<th>Positive</th>
<th>Negative</th>
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<tbody>
<tr>
<td>Better, safer products for consumers.</td>
<td>Will affect or eliminate business operations.</td>
</tr>
<tr>
<td>Generally good for vaping industry.</td>
<td>Number of smokers will increase.</td>
</tr>
<tr>
<td>Regulation will legitimize products.</td>
<td>Users will purchase online or from less reputable sources.</td>
</tr>
<tr>
<td>Number of ENDS users will increase.</td>
<td>Consumers’ costs will increase.</td>
</tr>
<tr>
<td>Consumers’ perceptions of vaping as a safe alternative to smoking will be adversely affected.</td>
<td></td>
</tr>
</tbody>
</table>

### Implications for FDA

- The qualitative study results showed that most owners were aware of local ENDS regulations such as prohibiting sales to minors.
- While most operators were aware of the lack of current federal ENDS regulations, there were some who believed that e-juices and devices were federally regulated.
- Areas of support for regulations identified by vape shop owners included e-juice and device safety and age of purchaser restrictions.
- Most owners voiced opposition to regulation of e-juice flavors, and many were against federal regulations because they were already self-regulating.
- Owners had mixed views on the likely impact of federal regulations. While some felt federal regulations would lead to safer products, most expressed concern that regulation would negatively impact their business.
- Efforts to educate vape shop operators on future regulations and penalties for non-compliance will be important.

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