Tobacco Product Regulation: FDA’s Economic Impact Analysis

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Advocacy Coordinating Committee
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FDA Economic Analysis

- **Benefits of Warning Labels**
  - Value of reduced smoking and life years gained
  - Value of health improvements from chronic diseases caused by smoking
    - Proposed rule included emphysema costs only
    - Added other health conditions in revised rule
  - Reductions in fire costs
  - Reductions in medical care costs
  - Other financial effects (e.g. social security payments, income tax receipts)
    - Not in proposed rule
FDA Economic Analysis

- **Costs of Warning Labels**
  - **One-time costs**
    - Costs of changing cigarette packaging
    - Costs of removing non-compliant point-of-sale advertising
    - Market testing costs
  - **Ongoing costs**
    - Industry’s administrative/record keeping costs
    - FDA’s administrative costs
Underestimate of Label Impact

- **Impact Estimate**
  - Accounts for changes in prices over time
  - Difference between projected and actual prevalence in Canada attributed to labels
  - 0.088 percentage point reduction (0.4% reduction in prevalence rate)
    - About 213,000 fewer smokers in US in 2013, growing over time

- **Underestimate of label impact due to inaccurate measure of price**
## Comparisons of Cigarette Prices in Canada Between Statistics Canada and the ITC Canada Survey Over Eight Waves of Survey Data Collection (October 2002 to June 2011)

<table>
<thead>
<tr>
<th>Survey Dates</th>
<th>Statistics Canada</th>
<th>Percent Change</th>
<th>ITC</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/30/02-12/30/02</td>
<td>131.3</td>
<td>4.7%</td>
<td>$7.43</td>
<td></td>
</tr>
<tr>
<td>5/15/03-9/28/03</td>
<td>137.4</td>
<td>4.7%</td>
<td>$7.69</td>
<td>3.5%</td>
</tr>
<tr>
<td>6/3/04-12/27/04</td>
<td>143.9</td>
<td>4.7%</td>
<td>$7.35</td>
<td>-4.4%</td>
</tr>
<tr>
<td>10/10/05-1/31/06</td>
<td>144.3</td>
<td>0.3%</td>
<td>$7.21</td>
<td>-1.9%</td>
</tr>
<tr>
<td>10/11/06-2/17/07</td>
<td>147.8</td>
<td>2.5%</td>
<td>$6.92</td>
<td>-4.0%</td>
</tr>
<tr>
<td>9/21/07-2/12/08</td>
<td>149.9</td>
<td>1.4%</td>
<td>$6.81</td>
<td>-1.6%</td>
</tr>
<tr>
<td>10/25/08-7/28/09</td>
<td>151.6</td>
<td>1.2%</td>
<td>$6.89</td>
<td>1.2%</td>
</tr>
<tr>
<td>7/13/10-6/24/11</td>
<td>157.1</td>
<td>3.6%</td>
<td>$7.13</td>
<td>3.4%</td>
</tr>
</tbody>
</table>

**Average Change**

2.6%  -0.5%

**Total Change**

19.7% -4.0%

Notes: The Statistics Canada price reflects an inflation-adjusted measure of the cigarette prices reported by Statistics Canada indexed to January 2000. The ITC price reflects a consumption-weighted average of the prices reported by smokers in the ITC Canada Survey, adjusted for inflation.
Cigarette Prices and Illicit Cigarette Market Share, Canada, 2000-2010

Source: Euromonitor, 2011, Statistics Canada, and ITC project. Note that the two price measures are indexed to 1.0 in November 2002
## Comparisons of Cigarette Prices in Canada Between BLS and the ITC Canada Survey Over Eight Waves of Survey Data Collection (October 2002 to June 2011)

<table>
<thead>
<tr>
<th>Survey Dates</th>
<th>BLS-CPI</th>
<th>Percent Change</th>
<th>ITC</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/30/02-12/30/02</td>
<td>1.180</td>
<td></td>
<td>$4.10</td>
<td></td>
</tr>
<tr>
<td>5/15/03-9/28/03</td>
<td>1.148</td>
<td>-2.7%</td>
<td>$3.85</td>
<td>-6.2%</td>
</tr>
<tr>
<td>6/3/04-12/27/04</td>
<td>1.141</td>
<td>-0.6%</td>
<td>$3.61</td>
<td>-6.1%</td>
</tr>
<tr>
<td>10/10/05-1/31/06</td>
<td>1.166</td>
<td>2.2%</td>
<td>$3.73</td>
<td>3.3%</td>
</tr>
<tr>
<td>10/11/06-2/17/07</td>
<td>1.186</td>
<td>1.7%</td>
<td>$3.89</td>
<td>4.2%</td>
</tr>
<tr>
<td>9/21/07-2/12/08</td>
<td>1.218</td>
<td>2.7%</td>
<td>$3.86</td>
<td>-0.7%</td>
</tr>
<tr>
<td>10/25/08-7/28/09</td>
<td>1.420</td>
<td>16.6%</td>
<td>$4.29</td>
<td>11.0%</td>
</tr>
<tr>
<td>11/2/09-1/10/10</td>
<td>1.644</td>
<td>15.8%</td>
<td>$4.76</td>
<td>11.1%</td>
</tr>
<tr>
<td>7/13/10-6/24/11</td>
<td>1.709</td>
<td>4.0%</td>
<td>$5.12</td>
<td>7.5%</td>
</tr>
<tr>
<td><strong>Average Change</strong></td>
<td></td>
<td>5.0%</td>
<td></td>
<td>3.0%</td>
</tr>
<tr>
<td><strong>Total Change</strong></td>
<td></td>
<td>44.9%</td>
<td></td>
<td>24.7%</td>
</tr>
</tbody>
</table>

Notes: Bureau of Labor Statistics inflation adjusted price indexed to one in January 2000. The ITC price reflects a consumption-weighted average of the prices reported by smokers in the ITC Canada Survey, adjusted for inflation.
Cigarette Prices and Illicit Cigarette Market Share, United States, 2000-2010

Source: Euromonitor, 2011, Bureau of Labor Statistics, and ITC project. Note that the two price measures are indexed to 1.0 in November 2002.
Underestimate of Benefits

- **Benefits excluded from FDA estimates**
  - Reductions in consequences of non-smokers exposure to tobacco smoke
    - Particularly reductions in infant/child health consequences from exposure to maternal smoking during pregnancy
  - Under-valuation of short-term health benefits from cessation
    - e.g. immediate drop in heart attacks
  - Long-term benefits given 20 year window for assessment
Underestimate of Benefits

- Reduction in benefits to account for lost consumer surplus
  - Initially assumed that 50% of value of extended/improved life was offset by loss of “consumer surplus” (satisfaction smokers get from smoking)
  - Final rule considered alternative scenarios but used similar approach
  - Implies considerable reduction in benefits or, in cost-effectiveness analysis, considerable increase in costs
Consumer Surplus
Consumer Surplus

- Price
- Quantity
- Supply
- Demand
- Demand, post-label
- \( P^* \)
- \( Q^* \)
- \( Q^{pl} \)
Underestimate of Benefits

- **Lost consumer surplus**
  - Assumes fully informed, fully rational behavior
  - Significant market failures in cigarette markets
    - Imperfect information about health consequences of tobacco use
    - Poor understanding of addiction
    - Almost all initiation occurs during adolescence
    - Time-inconsistency of preferences
Underestimate of Benefits

- **Lost consumer surplus**
  - Together result in most smokers regretting ever having started smoking
    - US-ITC survey: 91.2% agree or strongly agree that “if you had to do it over again you would not have started smoking”
    - 7 in 10 smokers report wanting to quit smoking completely
    - Over half of smokers try to quit for at least one day
      - Only 2.5% succeed in any given year
Underestimate of Benefits

- **Lost consumer surplus**
  - Levels of regret and quit behavior suggest that most of lost consumer surplus could be viewed as a benefit, not a cost
    - For smokers who quit, no longer spending to maintain an addiction that they’d prefer to break
    - For those prevented from initiation, benefits of avoiding an unwanted addiction not counted
  - FDA analysis also ignores gains in consumer surplus as money once spent on cigarettes is spent on other goods and services
    - Would offset nearly all of any lost surplus in the traditional analysis
Inconsistency of Approach

- **Lost consumer surplus**
  - Not included in economic analysis of other FDA proposed rules
    - e.g. 2011 regulatory impact analysis of Menu Labeling rules
  - Inappropriate for public health, public safety regulations
    - Same approach implies one should consider the “lost consumer surplus” to illicit drug users when assessing drug control laws or to drunken drivers when considering drinking and driving laws
Summary

- FDA Approach to Economic Impact Analysis Flawed
  - Under-appreciation of benefits
  - Reduction of benefits (or increase in costs) to account for lost consumer surplus
  - Likely to reappear in assessments of future rules
  - Misused in industry challenges to FDA regulation and other tobacco control policies