Calculating the “Benefits” of Smoking: How the FDA’s Economic Model Hinders Tobacco Regulation
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The Tobacco Control Legal Consortium

A national legal network supporting tobacco control policy change.
The Tobacco Control Legal Consortium

- PHAI The Public Health Advocacy Institute
- Public Health Law Center
- Smoke-Free Environments Law Project
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  SCHOOL OF LAW
  LEGAL RESOURCE CENTER
  FOR PUBLIC HEALTH POLICY
- New Jersey GASP
  Group Against Smoking Pollution
  and
  The Tobacco Control Policy and Legal Resource Center
- Center for Public Health and Tobacco Policy
Agenda

Desmond Jenson, J.D.
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Tobacco Control Legal Consortium

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Distinguished Professor of Economics,
University of Illinois at Chicago
Director, Health Policy Center
Institute for Health Research and Policy
Lost Pleasure? Consumer Surplus? Cost/Benefit Analysis???

In New Calculus on Smoking, It’s Health Gained vs. Pleasure Lost

For Policy Discouraging Smoking, FDA Defies Common Sense in Weighing 'Lost Pleasure' Against Health Benefits

Pleasure factor could override tobacco rules

FDA’s Misguided Concept of “Lost Pleasure” in Tobacco Regulation

Economists: FDA's tobacco rules underestimate health benefits

What is the FDA smoking?
Lost Pleasure? Consumer Surplus? Cost/Benefit Analysis???

In New Calculus on Smoking, It’s Health Gained vs. Pleasure Lost

For Policy Discouraging Smoking, FDA Defies Common Sense
Weighing 'Lost Pleasure' against Health Benefits

Pleasure factor counts in tobacco rules

What is the FDA smoking?
The Public Health Standard

Family Smoking Prevention and Tobacco Control Act requires the FDA to assess:

- Risks and benefits of users and non-users of tobacco products
- Impact on initiation
- Impact on cessation
Why does the FDA conduct a cost/benefit analysis?
Why does the FDA conduct a cost/benefit analysis?

Executive Order 12866 of September 30, 1993

For significant regulatory actions, agencies must provide:

- A draft of the regulation
- An assessment of anticipated benefits
- An assessments of anticipated costs
- An assessment of costs and benefits of alternative actions
Why does the FDA conduct a cost/benefit analysis?
The Role of the OIRA

1. OIRA Review of NPRM
2. NPRM Published
3. Comment Period
4. FDA Review of Comments

5. OIRA Review of Final Rule
6. Final Rule Published
7. Possible Litigation Challenge to Final Rule
8. Implementation of Final Rule
The Role of the OIRA

OIRA Review of NPRM → NPRM Published → Comment Period → FDA Review of Comments

OIRA Review of Final Rule → Final Rule Published → Possible Litigation Challenge to Final Rule → Implementation of Final Rule

8/9/14 - ???
The Role of the OIRA

OIRA Review of NPRM → NPRM Published → Comment Period → FDA Review of Comments

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8/9/14 - ???
The Role of the OIRA

10/1/13 – 4/24/14

OIRA Review of NPRM

205 days

4/25/14

NPRM Published

4/25/14 – 8/8/14

Comment Period

105 days

8/9/14 - ???

FDA Review of Comments

4/25/14

Final Rule Published

Possible Litigation Challenge to Final Rule

Implementation of Final Rule

OIRA Review of Final Rule
The Role of the OIRA

The act of deeming "deemed" tobacco products (except accessories) to be subject to the FD&C Act would result in significant benefits for the public health because it would provide FDA with critical information regarding the health risks of the newly deemed tobacco products. In addition, as described below, FDA would use its authorities to increase the likelihood that existing users will stop using these products and to decrease the likelihood that consumers will begin using them. Once deemed, tobacco products become subject to the FD&C Act and its implementing regulations, affording FDA additional tools to use to reduce the number of illnesses and premature deaths associated with the use of tobacco products. For example, it would provide FDA with critical information regarding the health risks of the newly deemed tobacco products including information derived from ingredient listing submissions and reporting of hazardous and potentially hazardous constituents required under the FD&C Act.

Deeming would provide FDA with information on the ability to determine the location and number of regulated entities and allow the Agency to establish effective compliance programs and better monitor the amount and types of products that are being sold to the public. If that deeming rule is finalized, it would also help to correct consumer misperceptions. Due to variations in the regulatory status of tobacco products, tobacco products not currently regulated by FDA are safe alternatives to currently regulated tobacco products (see section 11.C of this document). The act of deeming tobacco products as "Y.C." In addition, it would reduce the risk of misleading claims on the products to allow for better informed decisions making by consumers and would prohibit these products from being

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Why is the FDA’s cost/benefit analysis so important?
Why is the FDA’s cost/benefit analysis so important?

• Policy Experts

• Public Health Standard
Why is the FDA’s cost/benefit analysis so important?

- Policy Experts
- Public Health Standard
- Policy Generalists
- Cost/Benefit Analysis
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The Deeming Regulation’s Cost/Benefit Analysis

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements

Docket No. FDA-2014-N-0189

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
Office of Planning
Office of Policy and Planning
Office of the Commissioner
April 2014
An Evaluation of FDA’s Analysis of the Costs and Benefits of the Graphic Warning Label Regulation

Frank J. Chaloupka, University of Illinois at Chicago
Public Health Law Center Webinar
September 25, 2014
Tobacco Regulatory Economics Workgroup

• Frank J. Chaloupka, University of Illinois at Chicago
• Kenneth E. Warner, University of Michigan
• Daron Acemoglu, Massachusetts Institute of Technology
• Jonathan Gruber, Massachusetts Institute of Technology
• Fritz Laux, Northeastern State University
• Wendy Max, University of California, San Francisco
• Joseph Newhouse, Harvard University
• Thomas Schelling, University of Maryland
• Jody Sindelar, Yale University

TREW work supported by grant from the Robert Wood Johnson Foundation
Overview

• Federal agencies review of the FDA’s Regulatory Impact Analysis
  – Underestimated impact of graphic warning labels on cigarette smoking
  – Underestimation of the benefits from reduced smoking
  – Overestimation of the costs of implementing graphic warning labels
    • Counting the “Lost Pleasure” from reduced smoking

• Other Considerations

• Proposed Deeming Rule
Impact of Graphic Warning Labels on Tobacco Use
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
## 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>
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<tbody>
<tr>
<td>10/30/02-12/30/02</td>
<td>131.3</td>
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<td>5/15/03-9/28/03</td>
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<tr>
<td>10/11/06-2/17/07</td>
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<td>$6.92</td>
<td>-4.0%</td>
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<tr>
<td>9/21/07-2/12/08</td>
<td>149.9</td>
<td>1.4%</td>
<td>$6.81</td>
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<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>
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<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>
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<tr>
<td><strong>Average Change</strong></td>
<td></td>
<td><strong>2.6%</strong></td>
<td></td>
<td><strong>-0.5%</strong></td>
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<tr>
<td><strong>Total Change</strong></td>
<td></td>
<td><strong>19.7%</strong></td>
<td></td>
<td><strong>-4.0%</strong></td>
</tr>
</tbody>
</table>

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>
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<th>Percent Change</th>
<th>ITC</th>
<th>Percent Change</th>
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<td>10/25/08-7/28/09</td>
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<td>11.1%</td>
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<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>Average Change</td>
<td></td>
<td>5.0%</td>
<td></td>
<td>3.0%</td>
</tr>
<tr>
<td>Total Change</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 Label Impact

- Impact Estimate – Huang, Chaloupka and Fong (2014)
  - Modified FDA approach
    - Econometric model of graphic warning label impact on smoking prevalence
    - Pooled Canadian, US data
    - Controls for actual prices paid by Canadian, US smokers
  - Estimate that GWLs reduced Canadian smoking prevalence by 12.1-19.6%
    - At least 5.3 million fewer smokers (compared to FDA’s 213,000)
    - 12.5% reduction in prevalence
Underestimating the Benefits of Reduced Tobacco Use
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
Underestimate of Benefits

- **Benefits excluded from FDA estimates**
  - Reductions in consequences of non-smokers exposure to tobacco smoke
    - Estimated 41,000 premature deaths annually due to SHS exposure among non-smokers, 2005-2009
    - Assuming reduction proportional to reduced prevalence (low end estimate of 12.1%) implies almost 5,000 fewer deaths
    - At least $1.7 billion in increased productivity
    - Significant health care cost savings
Underestimate of Benefits

• Benefits excluded from FDA estimates
  – Reductions in infant/child health consequences from exposure to maternal smoking during pregnancy
    • Considerable short term costs
  – Exclusion of some health care services
    • Medications, home health care, and some outpatient care
  – Exclusion of injury costs in smoking-attributable fires
Underestimate of Benefits

• Other factors contributing to underestimate of benefits
  – Under-valuation of short-term health benefits from cessation due to assumption that reductions in health consequences evenly spread out over time
    • e.g. immediate drop in heart attacks and other cardiovascular consequences
  – Long-term benefits given 20 year window for assessment
  – Do not account for benefits from reduced cigarette consumption among continuing smokers
TREW Recommendations

• Include benefits to non-smokers from reduction in the health consequences of second-hand smoke exposure
• Include the short- and long-term benefits associated with reduced maternal smoking during pregnancy
• Include more comprehensive set of health care services
• Include injury costs averted by reduction in smoking-produced fires should be included
• Include benefits of reductions in smoking by continuing smokers
• Model the health impact of changes in smoking in a way that better accounts for the short-term benefits that result from reductions in use
Overestimating the Costs of FDA Regulations
FDA Economic Analysis

- **Costs of Warning Labels**
  - One-time costs - $319.5-518.4 million
    - Costs of changing cigarette packaging
    - Costs of removing non-compliant point-of-sale advertising
    - Market testing costs
  - Ongoing costs - $6.6-7.1 million annually
    - Industry’s administrative/record keeping costs
    - FDA’s administrative costs

- **Stopping at this point would have resulted in significant net benefits for GWL rule**
  - Particularly when using more recent estimates of the reductions in smoking prevalence
Overestimate of Costs

• 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

![Graph showing consumer surplus]

- Price
- Supply
- Demand
- Quantity
- $P^*$
- $Q^*$
Consumer Surplus

![Graph showing consumer surplus]

Price

Supply

Demand

Demand, post-label

Quantity

P*

Q^p

Q*
Overestimate of Costs

• **Lost consumer surplus**
  – Assumes fully informed, fully rational behavior
    • “Happy Addicts”
  – However, significant market failures in tobacco product markets
    • Imperfect information about health consequences of tobacco use
    • Poor understanding of addiction
    • Almost all initiation occurs during adolescence
    • Time-inconsistency of preferences
    • Under-appreciation of benefits of cessation
Overestimate of Costs

• **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 2.7% succeed in any given year
Overestimate of Costs

• **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
Overestimate of Costs

• **TREW approach**
  – “Principle of Insufficient Reason”
    • Benefits of quitting for those starting young should not be offset by lost consumer surplus
  – If use age 18 as threshold:
    • 77.3% of ever daily smokers first smoked before 18
    • 47.9% were daily smokers before 18
    • 70.3% started before age 17
    • Ignore 73.8-75.5% of “lost consumer surplus”
  – If use age 21 as threshold:
    • Ignore at least 91.8% of consumer surplus loss
Overestimate of Costs

– For those starting after age threshold
  • Still face considerable information failures
    – 2014 SGR identifies smoking as causing colorectal and liver cancer, macular degeneration, tuberculosis, diabetes, erectile dysfunction, rheumatoid arthritis, and reduced immune function; suggests link with breast and prostate cancer and asthma in adults
  • Additional biases in decision making:
    – Present bias – tendency to systematically overvalue immediate costs and benefits relative to future costs and benefits (impulsivity and self-control problems)
    – Projection bias – tendency to under-estimate the value of being smoke-free in the future
  • Importance of peer-effects
    – Marginalization of smoking given strong social norms against smoking lead to gains, not losses, from being smoke-free
Overestimate of Costs

TREW Conclusion:

“Given these issues, we conclude that nearly all of the 'lost pleasure' from tobacco use, as represented by conventionally measured consumer surplus, should not be included as a cost in FDA analyses of the economic impact of its tobacco regulations. The principle of insufficient reason suggests that the vast majority of any consumer surplus loss should be ignored given that most tobacco users become addicted regular users before reaching the legal purchase age. For those who do begin as adults, their imperfect information and self-control problems (and the associated psychological costs), increased consumer surplus from alternative consumption, and the importance of peer effects reflected in strong anti-tobacco norms suggest that regulations that reduce their tobacco use are more likely to be welfare enhancing than not. Indeed, the data strongly suggest that many smokers do not find smoking pleasurable and that they derive little consumer surplus from smoking. Instead, most are struggling with or avoiding the withdrawal they would experience if they were able to stop smoking and break an addiction they regret having ever started, facing psychological costs from being addicted and lacking the self-control to quit.”
Other Considerations

- Smoking and “Happiness”
‘Happiness’ Literature

  - Subjective data on well being, propensity to smoke in US, Canada from General Social Surveys (1973-1998 in US; various years 1985-1998 in Canada)
  - Happiness measures:
    - US: “taken all together, how would you say things are these days – would you say that you are very happy, pretty happy, or not too happy?”
    - Canada: “would you describe yourself as very happy, somewhat happy, somewhat unhappy, very unhappy, or no opinion?”
  - For US: “we find consistent evidence that excise taxes make those who have a propensity to smoke happier”; comparable findings for Canada
  - True for cigarette excises but not other excises
‘Happiness’ Literature

  – Assess impact of French workplace smoking ban
  – Unhappy smokers defined as those who consult tobacco cessation services
  – Find that smoking ban increases demand for cessation services and increased likelihood of successful quitting
  – Conclude that “workplace smoking bans might be welfare improving since they seem to help ‘unhappy addicts’ to reconcile their behavior with their preferences
‘Happiness’ Literature

• Wang, et al., “Ex-smokers are happier than current smokers among Chinese adults in Hong Kong”, *Addiction*, 2014
  – Cross-sectional analysis of 2009-12 survey data on 4,553 Chinese adults in Hong Kong
  – 2 ‘happiness’ measures:
    • 4 item subjective happiness scale (absolute happiness, happiness relative to peers, two descriptive happiness/unhappiness measures; 1-7 scale)
    • Single item global happiness index (very happy, happy, not too happy, very unhappy)
  – Ex-smokers are significantly happier than current smokers on both measures
  – Current and never smokers similar on both
  – Smokers not trying to quit happier than smokers who try to quit but haven’t succeeded
‘Happiness’ Literature

  - Cross-sectional analysis of survey data on 879 former smokers in the UK
  - Retrospective question about whether or not they felt happier now, less happy, or about the same compared to when they were smoking
  - 69.3% reported feeling happier than when they were smoking
    - 3.3% reported feeling less happy
    - Greater happiness among younger ex-smokers and those who had quit more than one year prior to survey
‘Happiness’ Literature

• Shahab & West, “Differences in happiness between smokers, ex-smokers and never smokers: cross-sectional findings from a national household survey,” *Drug and Alcohol Dependence*, 2012
  – Cross-sectional analysis of survey data on 6923 adults in the UK collected for the Smoking Toolkit Study
  – 2 happiness measures:
    • ‘all things considered, how satisfied are you with your life as a whole?’ (5 point scale)
    • “some people are generally very happy. They enjoy life regardless of what is going on, getting the most out of everything. To what extent does this characterisation describe you?” (7 point scale)
  – Former smokers for one year or more significantly happier than current smokers; similar to never smokers
  – More recent quitters similar to current smokers
‘Happiness’ Literature

- Weinhold, “Happiness and Smoking”, manuscript, London School of Economics, August 2014
  - Cross-sectional and longitudinal analysis of 2007-13 Longitudinal Internet Studies or the Social Sciences survey data on over 8,000 Dutch adults
  - Two measures:
    - Average of responses to questions on “how happy would you say your are”, “how satisfied are you with the life you lead at the moment”, and “to what degree do you consider yourself happy” (1-10 scale)
    - Single item “how do you feel at the moment” (1-7 scale)
  - No evidence of any loss of happiness among those who have quit, in either short or long run
  - “Strong suggestive evidence that quitting smoking doesn’t affect well-being in the short-run, and if anything likely increases overall life satisfaction”
‘Happiness’ Literature

  - Longitudinal data on 1504 smokers enrolled in long-term cessation trial in Madison and Milwaukee
  - Multiple subjective measures of well-being:
    - Global quality of life (composite based on 17 subscales), health related quality of life, positive and negative affect scale, life stressors, and relationship satisfaction
  - Quitters show improvement over time in most measures (all but marital satisfaction) compared to continuing smokers
‘Happiness’ Literature

  - Review of 26 longitudinal studies assessing mental health before cessation and at least six weeks after cessation
  - Multiple outcomes:
    - Anxiety, depression, psychological quality of life, positive affect, stress
  - Quitters show improvement over time in anxiety, depression, mixed anxiety and depression, stress, psychological quality of life, and positive affect, compared to continuing smokers
    - No evidence of differences in effect size between general population and populations with physical or psychiatric disorders
    - Effect sizes as large or larger than those for antidepressant treatment
‘Happiness’ Literature

  - Annual state-level suicide rates from 1990-2004 linked to state cigarette excise tax rates and smoke-free air policy indicators
  - Higher taxes, stronger smoke-free policies, and combined policy index associated with lower suicide rates
    - Stronger association among populations where predicted smoking prevalence was highest and vice-versa
‘Happiness’ Literature

• Conclusion
  – Successful quitters ‘happier’ than continuing smokers
    • “happiness” among former smokers increases over time

• Suggests that no ‘lost pleasure’ from quitting, but rather improved well-being that should be counted as a benefit
Proposed Deeming Rule
HI, KIDS! YOUR OL’ PAL, MR. BUTTS HERE, AND BOY, DO I HAVE NEWS!

GET THIS!

“I’M A COST-BENEFIT ANALYST, THE FDA SAYS THE PLEASURES OF SMOKING OFFSETS THE COSTS BY 70%!”

HALLELUJAH! ABOUT TIME!

THE FDA IS FINALLY ADMITTING THAT THE PLEASURE OF ADDICTION IS A BENEFIT!

A BENEFIT WHICH DISCOUNTS THE “COSTS” OF SMOKING – ALL THOSE PAINFUL EARLY DEATHS – BY 70%!

70%! WHY, THAT’S ALMOST A WASH!

So Light Up Today, Kids, and Enjoy Those Benefits!

Thank You for Smoking!
Summary & Conclusions
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
  – Worse in proposed ‘deeming’ rule
  – Misused in industry challenges to FDA regulation and other tobacco control policies
  – Potential to undermine FDA tobacco regulation and other public health regulations
For more information:

http://www.tobacconomics.org

@tobacconomics

fjc@uic.edu
Where to Find Information about FDA Regulation

FDA Tobacco Action Center

In June 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act, giving the Food and Drug Administration unprecedented authority to protect the public health by regulating tobacco products. The ultimate success of the law will depend on an active and engaged public health community that works to support the FDA with the best evidence and input available.

Take Action Today

Tell the FDA to Address Illicit Trade

Public health groups are petitioning the FDA to implement a track and trace program to combat illicit trade. Submit your comment supporting this petition.

Report Violations of the Tobacco Control Act

Help the FDA enforce the Tobacco Control Act and protect public health by reporting retailer and industry violations you see in your community.

Tell the FDA to Reject Lorillard’s Petition

Lorillard wants the FDA to expand a loophole to allow it to market new tobacco products without waiting for premarket approval. Tell the FDA to protect public health by rejecting the petition.

Action Opportunities

Sign up to receive our FDA Tobacco Action Alerts notifying you of opportunities to strengthen FDA regulation of tobacco.
Questions?

Questions Now:
• Q&A panel on your screen

Questions Later:
• publichealthlawcenter.org – click on FDA Tobacco Action Center
• desmond.jenson@wmitchell.edu
• 651-695-7612