Tobacco Product Licensing, Production & Distribution

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Developing Public Health Regulations for Marijuana: Lessons from Alcohol and Tobacco
Arlington, VA, February 11 2013
Licensing
Licensing – Aims

- **Supply chain control**
  - Identification & monitoring
  - Tax collection
  - Minimization of tax evasion
  - Enforcement

- **Restrict availability of tobacco products**
  - Number, type and location of retailers

- **Increase costs, prices and revenues**
Supply Chain Control

- Licensing of all engaged in tobacco production and distribution
  - Producers
  - Wholesalers/distributors
  - Importers/exporters
  - Retailers

- Tracking and tracing of all products
  - Monitoring of production and distribution
  - Unique, encrypted pack markings
Supply Chain Control

- **Effective tax collection**
  - Licensing, monitoring, and track & trace system coupled with enforcement to ensure all taxes paid
  - Identify where tax evasion is occurring

- **Enforcement**
  - Sufficient resources needed for enforcement
  - Swift, severe penalties
  - Suspension/revocation of license
  - Administrative sanctions
Combating Tax Evasion

- California’s high-tech tax stamp
  - Adopted 2002; fully implemented 2005
  - Coupled with better licensing standards
  - Examined with hand-held scanners
  - Thousands of compliance checks, hundreds of citations
  - Generated over $124 million in revenues during 20 month period (mid-2004 through late 2005)
Combating Tax Evasion

- Illicit Trade Protocol to WHO Framework Convention on Tobacco Control
  - Adopted late 2012; recently opened for signature
  - Licensing and other supply chain controls
  - Production monitoring
  - Tracking and tracing
  - Enforcement and swift, severe sanctions
  - International cooperation
  - Information sharing
Cigarette tax and illegal cigarette market, Italy. 1991-2008

Italy: Size of cigarette contraband market & total tax on cigarettes

- Total tax incidence
- % of contraband

<table>
<thead>
<tr>
<th>Year</th>
<th>Total tax as % of most popular brand price</th>
<th>% of contraband market in duty paid sales</th>
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<td>1991</td>
<td>71%</td>
<td>15%</td>
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<td>72.6%</td>
<td>12%</td>
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<td>1993</td>
<td>73%</td>
<td>11%</td>
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<td>1994</td>
<td>73%</td>
<td>6%</td>
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<tr>
<td>1995</td>
<td>74.5%</td>
<td>3%</td>
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<td>1998</td>
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<td>1%</td>
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<tr>
<td>2008</td>
<td>75%</td>
<td>2%</td>
</tr>
</tbody>
</table>
Restricting Availability

- Primarily through licensing of retailers, including restrictions on:
  - Types of business that can sell tobacco products
    - e.g. recent limits on sales in pharmacies
  - Location of tobacco retailers
    - Primarily near schools, parks, other youth venues
  - Density of tobacco retailers
    - Based on population, geography
  - Mode of sales
    - bans on vending machine sales, self-service
Model Licensing Ordinance

Key Provisions include:

- Licenses limited by population and density
- No licenses near schools/youth areas
- No licenses in residential zones
- No licenses for bars and restaurants
- License revocation for violating storefront signage laws or age-of-purchase laws
- No sales of single cigars or tobacco look-alike products
- No free tobacco product sampling

www.changelabsolutions.org, Leighton, et al., 2013
Revenue Generation

• Set licensing fee to cover enforcement expenses
  o Personnel: Police Department, City Clerk, Attorneys, Youth Decoys
  o Equipment
  o Training materials
  o Administrative & overhead
  o Data visualization

• Calculator available from ChangeLab Solutions

www.changelabsolutions.org, Leighton, et al., 2013
Impact on Tobacco Use

- **Very limited evidence to date:**
  - Tobacco marketing more prevalent in stores near schools and/or frequented by youth
  - Exposure to tobacco marketing increases prevalence and initiation of youth tobacco use
  - Exposure to marketing reduces likelihood of cessation and increases relapse

- **A few studies find:**
  - Youth prevalence higher in neighborhoods with greater outlet and/or advertising density
  - Strong licensing laws associated with fewer sales to minors

Change Lab Solutions, 2012; Tobacco Control Legal Consortium, 2012; USDHHS, 2012
Other Proposals

- **Significant licensing fees**
  - Much higher than current retail licensing fees to raise costs/prices and government revenues

- **Brand licensing fees**
  - To reduce brand proliferation, raise costs/prices and government revenues

- **Limit number of licensed brands**
  - To reduce brand proliferation
Product Regulation
TUNE IN. SMOKE OUT.

Smokers, SWITCH to Camel SNUS and never miss a note. Camel SNUS is smoke-free, spit-free, drama-free tobacco packed in a pouch for enjoyment virtually anywhere, anytime. Camel SNUS – the pleasure’s all yours.

camelsnus.com

Visit bluarrs.com
Elements of product regulation

- Packaging and labeling
  - Including colors, imagery, descriptors, warnings
- Product design
  - Including nicotine, tar, CO, and other constituents
- Product availability
  - Including limits on where sold, complete bans

Potentially competing goals:

- Reduce consumption of tobacco products
- Reduce harms caused by tobacco consumption
  - Individual level vs. population level
Product Regulation

- Challenges to tobacco product regulation
  - Diversity of tobacco products
    - Wide range of tobacco products available globally
    - Differences in design of same product/brand in different places
    - New products seem to emerge continuously
  - Diversity of tobacco industry
    - Increasing concentration globally
    - Increased range of tobacco products
    - Adaptability in response to tobacco control policies
Product Regulation

- Challenges to product regulation
  - Lack of regulatory capacity and lack of information
    - Little to no information on long-term consequences of use of emerging products
    - Challenges to measuring risk exposure
    - Questions about net impact on number of users, types of products consumed
  - Potential for harm
    - E.g. initial support for light and low-tar cigarette brands
US Background

- Historically, tobacco products largely unregulated
  - In contrast to significant regulation of pharmaceutical nicotine products
- FDA Commission David Kessler’s effort to gain authority over tobacco products
  - Initiated 1994 – two key elements: tobacco use as a pediatric disease and tobacco products as highly engineered drug delivery devices
  - FDA rules issued in 1996; started with focus on youth access
  - FDA jurisdiction over tobacco struck down in March 2000 by US Supreme Court
Product Regulation

- **Family Smoking and Prevention Act of 2009**
  - Tobacco program created at FDA
    - Paid for by industry fees
    - Allows ‘fast track’ approval of cessation products
  - Banned flavored cigarettes, eff. 9/22/09
    - Excludes menthol flavored cigarettes
    - Doesn’t covered other flavored products (small cigarettes, cigarillos, smokeless,....)
  - Restrictions on sale and marketing to youth, April 2010
Product Regulation

- Family Smoking and Prevention Act of 2009
  - Brand specific disclosure of product constituents required January 2010
  - Currently trying to figure out how best to communicate risk
Constituent Labeling

EMISSION NUMBERS

European Union

Source: Hammond 2009
Constituent Labeling

“DESCRIPTIVE” INFORMATION

- Smoking exposes you to more than 40 harmful chemicals.
- These chemicals damage blood vessels, body cells and the immune system.
- QUIT NOW to reduce your risk of chronic illness or premature death.

Australia

Source: Hammond 2009
Constituent Labeling

CONSTITUENT INFORMATION

"Toxic emissions / unit:” “Tar” 14 - 35 mg, Nicotine 1.1 - 2.7 mg, Carbon monoxide 14 - 30 mg, Formaldehyde 0.055 - 0.14 mg, Hydrogen cyanide 0.14 - 0.36 mg, Benzene 0.043 - 0.097 mg

“Émissions toxiques / unité:” “Goudron” 14 - 35 mg, Nicotine 1.1 - 2.7 mg, Monoxyde de carbone 14 - 30 mg, Formaldéhyde 0.055 - 0.14 mg, Acide cyanhydrique 0.14 - 0.36 mg, Benzène 0.043 - 0.097 mg

CANADA

Source: Hammond 2009
Constituent Labeling

CANADA vs. EU vs. AUSTRALIA (8mg)

"Most useful" 74%
"Least useful" 5%

Source: Hammond 2009
Product Regulation

- Family Smoking and Prevention Act
  - Ban on misleading descriptors, July 2010
    - Light, low-tar, mild, etc.
“Replacement” Descriptors

Replacement Additives

- Full Flavor
- Lights
- Ultra Lights

- Green Label
- Gold Box
- Silver Box
Family Smoking and Prevention Act of 2009

- New warning labels:
  - On smokeless products, July 2010
  - Large, graphic warnings on cigarettes, initially to be required by October 2012
  - Currently on hold in courts over First Amendment issues
WARNING: Tobacco smoke can harm your children.
1-800-QUIT-NOW

WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
1-800-QUIT-NOW

WARNING: Smoking can kill you.
1-800-QUIT-NOW

WARNING: Cigarettes cause strokes and heart disease.
1-800-QUIT-NOW

WARNING: Cigarettes cause cancer.
1-800-QUIT-NOW

WARNING: Cigarettes are addictive.
1-800-QUIT-NOW

WARNING: Quitting smoking now greatly reduces serious risks to your health.
1-800-QUIT-NOW

WARNING: Smoking during pregnancy can harm your baby.
1-800-QUIT-NOW
Warning Labels

Singapore 2004

Venezuela 2005

Source: Fong 2009; Hammond 2009
Thailand, 2005

Australia, 2006

Hong Kong, 2007

Belgium 2008

Source: Fong 2009; Hammond 2009
Iran, 2009

Egypt, 2008

Malaysia, 2009

Peru, 2009

Source: Fong 2009; Hammond 2009
Warning Labels

Summary

- Strong, prominent warning labels:
  - More likely to be noticed
  - Increase risk perceptions
  - Raise intentions to quit
  - Increase quit attempts
  - Reduce prevalence
- Graphic pictorial warnings more effective than text only warnings
- Marginal effect greater in LMICs
  - Less history of tobacco control, lower awareness of health consequences
- Highly cost-effective intervention
Product Regulation

- **Family Smoking and Prevention Act of 2009**
  
  - Gives FDA authority to
    - Establish product standards
    - Ban/reduce various constituents, including mandating reduction in nicotine delivery
Global experiences

- Mandated reductions in toxic constituents
  - United Kingdoms’ “low tar programme”
    - Began in early 1970s with measurement, publicity on tar and nicotine content
    - Expanded to include CO in 1981
    - 1980 agreement with industry to reduce sales weighted average tar per cigarette to 15 mg by 1983; 13 by 1987
    - Stronger limits imposed by EU in 1992 – reduced to 12 by 1998; 10 by 2005
  - Similar policies in several other countries
  - Little evidence of positive impact
    - Most analysts suggest that these policies are harmful given perceptions they create that products have reduced risks
Product Regulation

- Global experiences
  - Reducing fire risk
    - "fire safe" or "reduced ignition propensity" policies
      - First adopted in New York State, June 2004
      - Comparable policies in other states and countries
      - Has significantly reduced burn length of cigarettes in markets with such policies
      - Early evidence that fires caused by smoking fall
      - Potential unintended consequences include increased delivery of tar, CO, nicotine and other constituents, and false sense of security leading to riskier behavior
Product Regulation

- Family Smoking and Prevention Act
  - FDA approval of any new tobacco products
    - Issues with ‘substantial equivalence’ of new and existing products
  - Eliminates federal preemption of strong state restrictions on marketing and more
Plain Packaging

- **Australia first to adopt**
  - Announced April 29, 2010
  - Legislation introduced April 7, 2011
  - Passed House August 24, 2011, Senate November 2, 2011
  - Phased in as of December 1, 2012
  - Prohibits use of trade marks, symbols, graphics or images on pack
  - Allows brand, business/company name, variant name in standard font/position

- **Coupled with other provisions**
  - Graphic warnings expanded (75% front, 90% back)
  - Pack/cigarette specifications
  - Similar details for other tobacco products
Plain Packaging

- **Subject to multiple challenges from tobacco industry**
  - Constitutional challenge to be heard in high court April 2012
  - Philip Morris challenge under Bilateral Investment Treaty with Hong Kong (expropriation of intellectual property)
    - PM-Asia acquired PM-Australia on February 23, 2011
  - Ukraine, Honduras, Dominican Republic challenge under the Trade Related Aspects of Intellectual Property Rights (TRIPS) and other agreements
  - Will be resolved in coming months/years

- **Similar policies progressing in other countries**
Lessons Learned
Prevalence – Cigarettes & Marijuana

Source: Monitoring the Future, 2012
Lessons Learned

- Strong control over production and distribution
  - Licensing of all involved
  - Sizable license fees
  - Annual review/renewal of licenses
  - Production monitoring
  - Tracking and tracing
  - Aggressive enforcement
  - Swift, severe penalties
  - Strong limits on outlet density, location and type
Lessons Learned

- Strong controls on packaging and labeling
  - Large graphic warnings
  - Plain/standardized packaging
  - Disclosure of product constituents

- Effective product regulation
  - Controls on product constituents and characteristics
    - Including THC content
  - Pre-market product approval of all products
For more information:

fjc@uic.edu

www.bridgingthegapresearch.org

www.tobacconomics.org (coming soon)