

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)



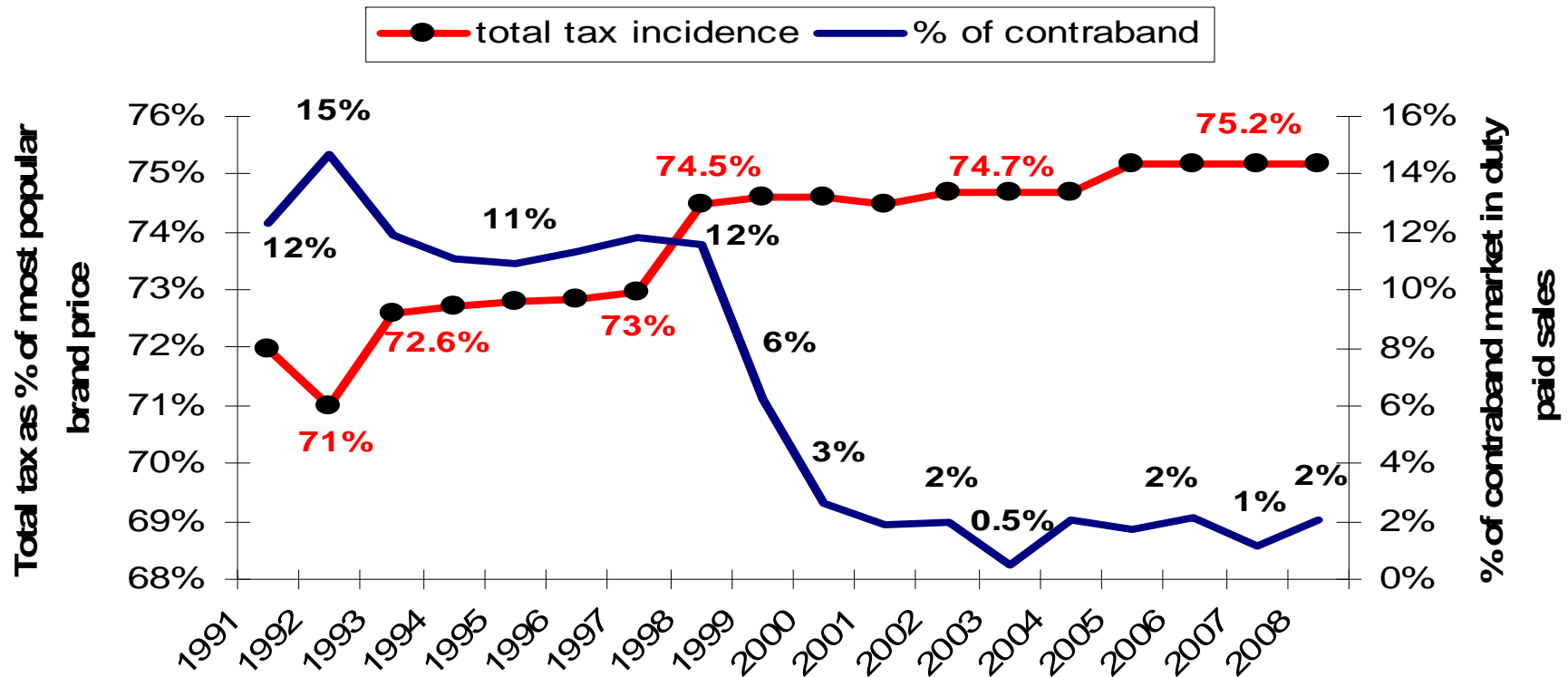
Combating Tax Evasion

- 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



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

Rev. 8/10
Massachusetts Department of Revenue

Form CT-RL
Application for Tobacco Retailer License

This application is for a tobacco retailer license for the period October 1, 2010 through September 30, 2012. Please read the instructions below. License fee is \$50 for over-the-counter cigarette sales, and \$50 for each cigarette vending machine. Complete a separate application for each vending machine. There is no fee if you are only selling cigars and/or smoking tobacco.

Registration Information. Please print. **Note:** You must be registered for sales tax before applying.
How are cigarettes sold? Over the counter Vending machine
Please check all that apply: Cigarettes Cigars and/or smoking tobacco

Legal name of business	Federal identification number	Application number (DOR use only)		
Mailing address	City/Town	State	Zip	CODE-3 Telephone
Trade name				
Street address of retail sale location	City/Town	State	Zip	Telephone
Name(s) of owner(s)	Type of business	E-mail address		

I hereby certify that I agree to conform with the provisions of the Massachusetts General Laws, Chapters 62C and 64C, as amended, and with all rules and regulations made thereunder, and have complied with all laws of the Commonwealth relating to taxes. Signed under the penalties of perjury.

Signature _____ Title _____ Date _____

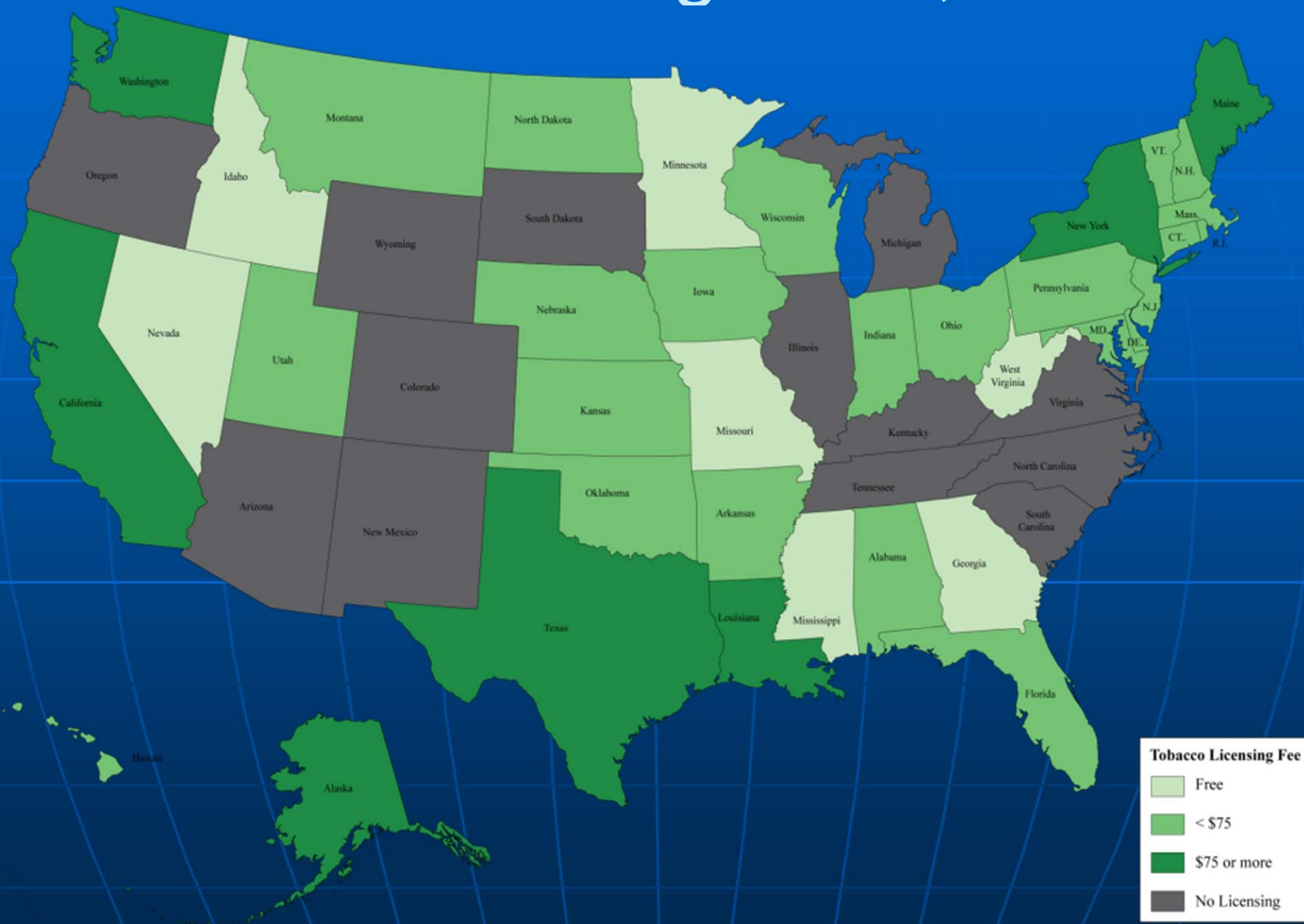
Mail to: Massachusetts Department of Revenue, PO Box 7004, Boston, MA 02204.

General Instructions
You must obtain a tobacco retailer license before purchasing and selling cigarettes and/or cigars and smoking tobacco. **You must be registered to collect sales tax before applying for a tobacco retailer license.** If you have not registered for sales tax, go to DOR's website at www.mass.gov/dor or call the Customer Service Bureau at (617) 887-MDOR.
Enter all information on application as shown on sample.
Check the box which indicates how you sell cigarettes (cigarettes include "little cigars" and smokeless tobacco). If you sell cigarettes over the counter, there is a \$50 fee for obtaining or renewing your license. If you sell cigarettes in vending machines, there is a \$50 fee for each machine. Complete a separate application for each vending machine. There is no fee if you are only selling cigars and/or smoking tobacco.
Legal name of business. Enter the legal name of your business for mailing purposes. For most retailers this will be the same as their trade name.
Federal identification. Enter your Federal Identification (FID) number. Under Massachusetts law, if you are not a sole proprietor, you must have a FID number to sell cigarettes and/or cigars and smoking tobacco.
Mailing address. If you want your application sent to a location other than the retail sale location, enter that address here. Be sure to include the Zip code. Also enter your telephone number for that address, including the area code.
Trade name. If the retail sale location is different from the mailing address, enter the trade name of the retail sale location here. If the retail sale location and mailing address are the same, leave this section blank.

Address of retail sale location. Enter the address of the retail sale location. If this address is the same as the mailing address, leave this section blank. Also enter the telephone number for the sale location, including the area code.
Enter the name(s) of the owner(s) of the business.
Enter the type of business in which you sell cigarettes, cigars and/or smoking tobacco; for example, grocery store, gas station, etc.
Enter the e-mail address, if any, of the business owner.
Signature. Be sure to sign your name above, and enter your title and the date on this application. Your application will not be processed without your signature. Make your check(s) payable to the Commonwealth of Massachusetts. Mail your application along with any required fee to: **Massachusetts Department of Revenue, PO Box 7004, Boston, MA 02204.**

<http://www.mass.gov/Ador/docs/dor/Cigarette/PDFs/CT-RL.pdf>

State Licensing Laws, Fees



Source: Leighton, et al., 2013

© American Lung Association, March 2011

Model Licensing Ordinance

Licensing Ordinance Checklist

A local licensing ordinance can be used to effectively enforce all laws that apply to tobacco sales.

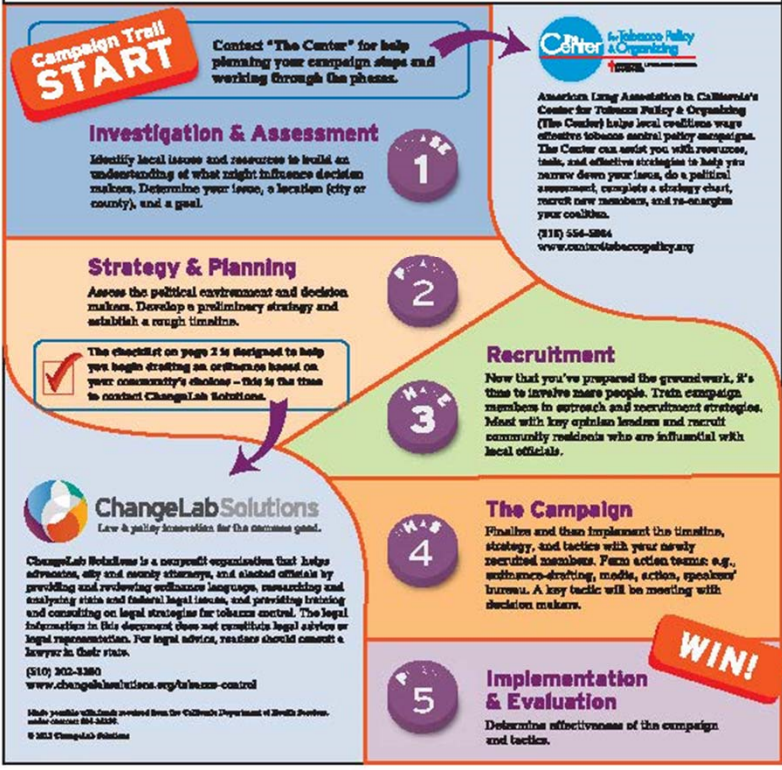
A licensing ordinance not only requires retailers to obtain a license to sell tobacco products but also provides meaningful penalties if the merchant sells tobacco to minors or violates any other law related to tobacco sales. For

retailers who continue to violate these laws, licensing offers a means to eliminate them from the tobacco product marketplace.

ChangeLab Solutions' *Model California Ordinance Requiring a Tobacco Retailer License* and its accompanying 'plug-in' provisions provide a range of policy options to consider when designing a local

licensing ordinance. The ordinance language you select should be part of a larger strategy to have the ordinance adopted in your community.

To guide your planning, the American Lung Association in California's Center for Tobacco Policy & Organizing has developed the five phase model below.



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

Revenue Generation

- Set licensing fee to cover enforcement expenses
 - Personnel: Police Department, City Clerk, Attorneys, Youth Decoys
 - Equipment
 - Training materials
 - Administrative & overhead
 - Data visualization
- Calculator available from [ChangeLab Solutions](http://www.changelabsolutions.org)

To receive a Microsoft Excel file instead of pdf, return to the form and request "Email Delivery"

Tobacco Licensure Costs						
	OT Yrs	Number of Staff	Hours	Salary Rate	Wages	Fringe Expense
Program Start Up Costs						
Police Department						
Develop policy/procedural/procedure						
Compile a roster list of retailers						
Coordinate with Prosecuting Attorney						
Rebate situation						
Other						
Fringe Benefit %						
City Clerk (Business License Dept.)						
Fringe Benefit %						
Total Program Start Up Costs						
Total Number of Stores in Enforcement Area						
Start Up Cost Per Store						
Police Dept. Enforcement Expenses						
Personnel Costs						
Preparation (Officer/ sergeant)						
Recruitment and training and expenses						
Get equipment						
Operational plan and enforcement packets						
Conducting the operation						
Officers						
Sergeant						
Dispatcher						
Follow up (Officer/Dispatcher/Administrative)						
File Cases						
Violation and make up letters						
Station						
Meals coverage						
Fringe Benefit %						
Other Expenses						
Evidence						
Buy Money						
Food for Participants						
Youth decoy incentives						
Misc. Supplies						
Total Expenses Per Operation						
Number of Operations Per Year						
Number of Retailers Inspected Per Operation						
Total Number of Retailers Inspected Per Year						
Total Enforcement Cost Per Year						
Number of Tobacco Retailers in City						
Enforcement Cost Per Retailer						
Administrative Expenses						
Finance Dept. Personnel Costs						
Process Application						
Prepare and Issue Licenses						
Maintain Database						
Collect Fees						
Fringe Benefit %						
Other Finance Dept. Expenses						
Postage						
Licenses						
Applications						
Misc. Supplies						
Suspension Hearings						
Finance Dept. Personnel						
Fringe Benefit %						
Police Dept. Personnel						
Fringe Benefit %						
Total Administrative Expenses Per Year						
Administrative Cost Per Retailer						
Total Licensure Cost Per Tobacco Retailer						

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

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



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BREAK FREE

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*
*WEBSITE RESTRICTED TO AGE 21+ TOBACCO CONSUMERS.

SNUS

WHY QUIT? SWITCH TO BLU

blu is the smart choice for smokers wanting a change. Take back your freedom to smoke when and where you want without ash or smell. blu is everything you enjoy about smoking and nothing else. Nobody likes a quitter, so make the switch today.

Visit blucigs.com

PREMIUM ELECTRONIC CIGARETTE

18+ only | CALIFORNIA PROP 65 WARNING: This product contains nicotine, a chemical known to cause cancer in some animals. Use only as directed.

Product Regulation

- 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

Product Regulation

■ 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

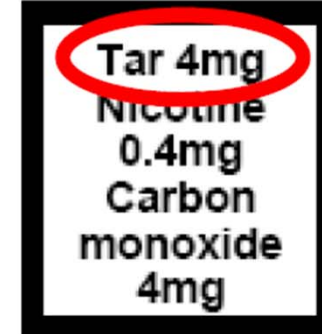
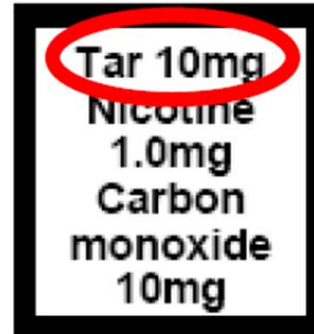
- Family Smoking and Prevention Act of 2009
 - Brand specific disclosure of product constituents required January 2010
 - Currently trying to figure out how best to communicate risk

Constituent Labeling

EMISSION NUMBERS



European Union



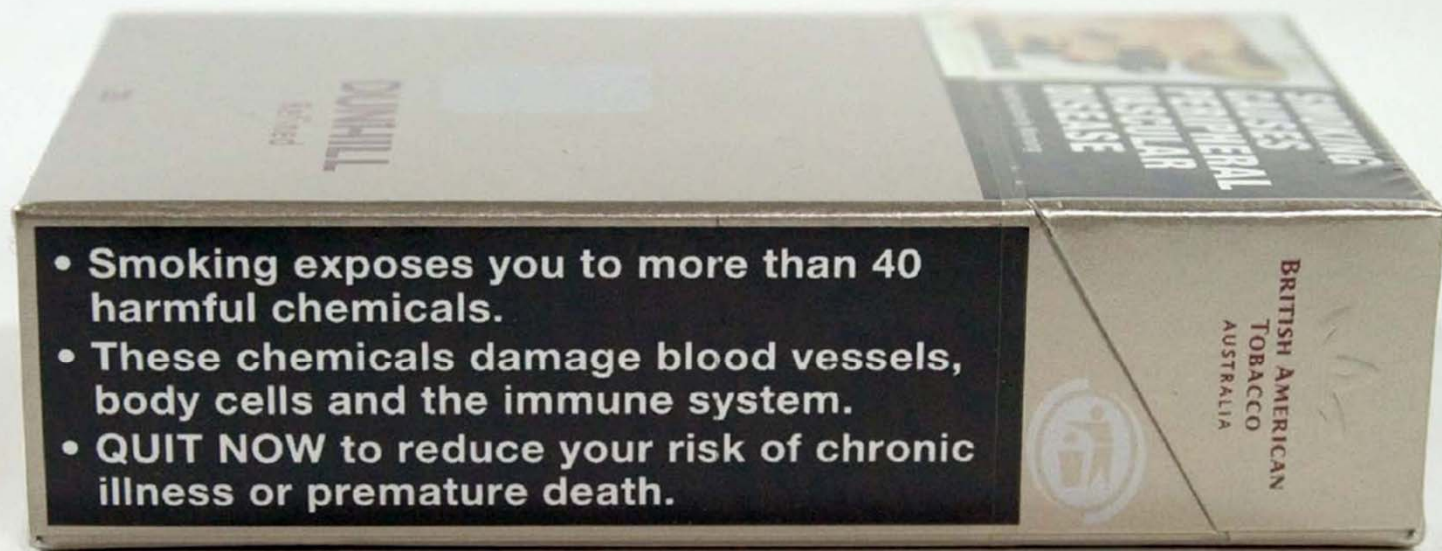
➔ 9 out of 10 smokers believe that lower numbers means lower risk.

Source: Hammond (2007)



Constituent Labeling

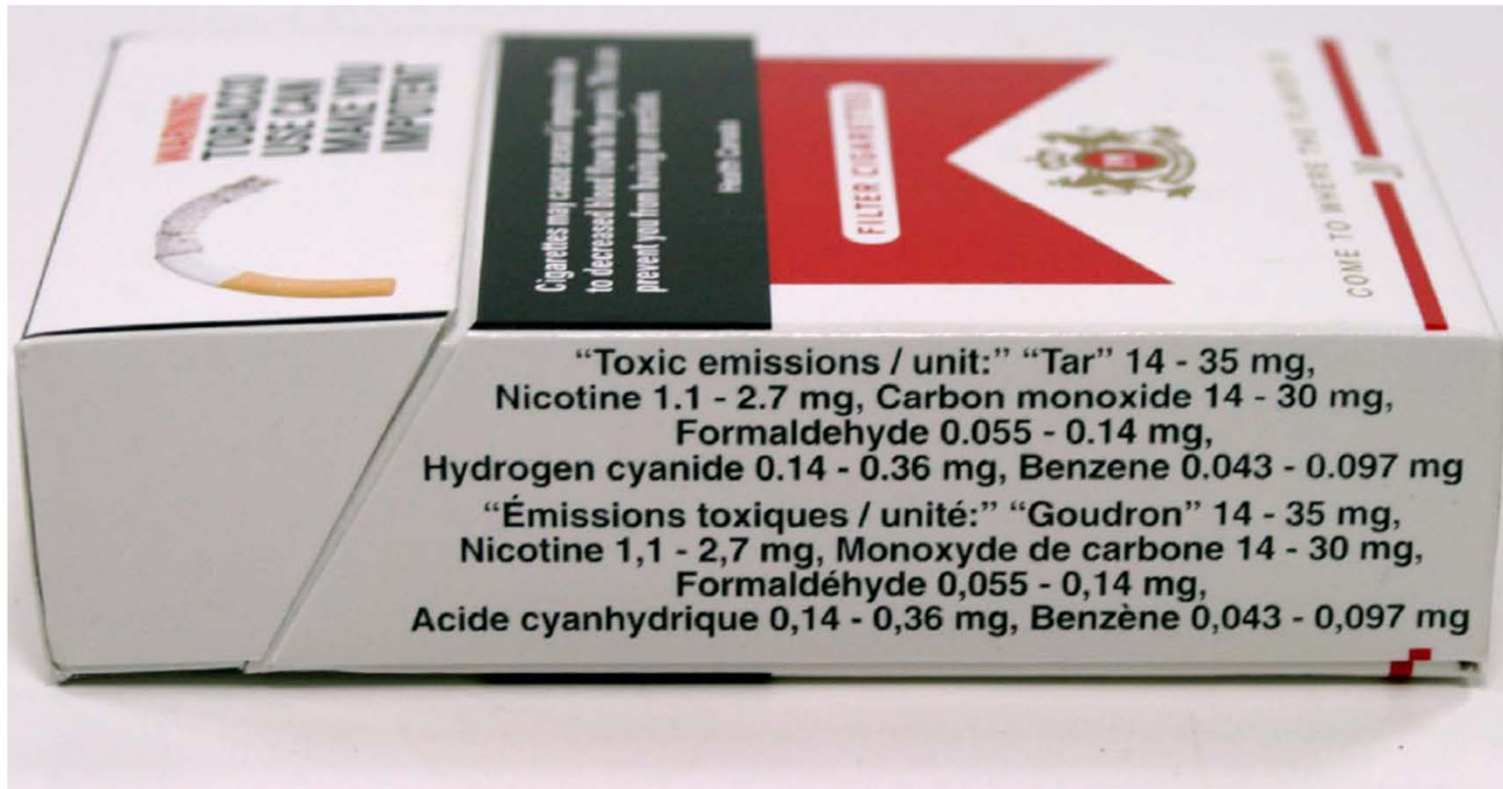
“DESCRIPTIVE” INFORMATION



Australia

Constituent Labeling

CONSTITUENT INFORMATION

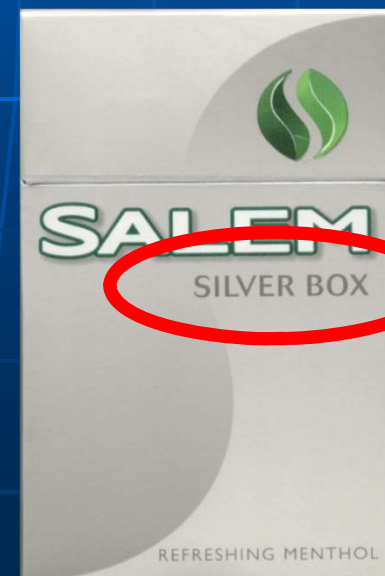
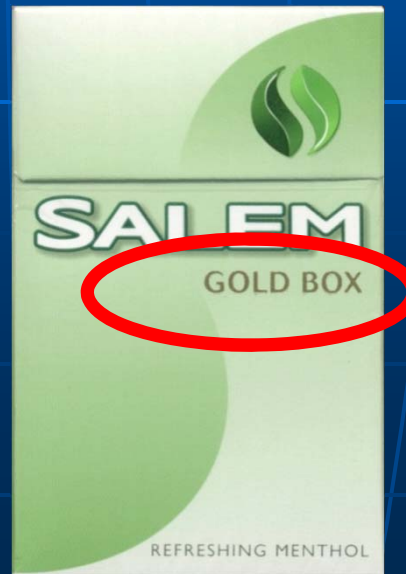
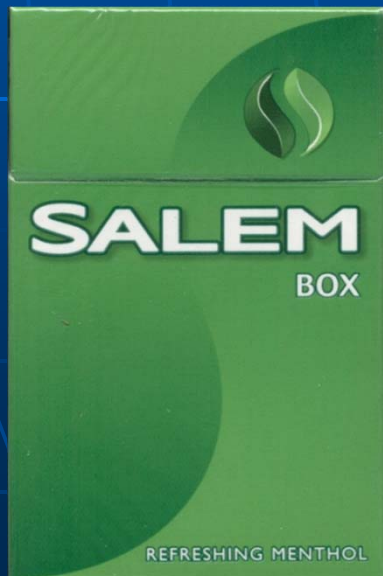
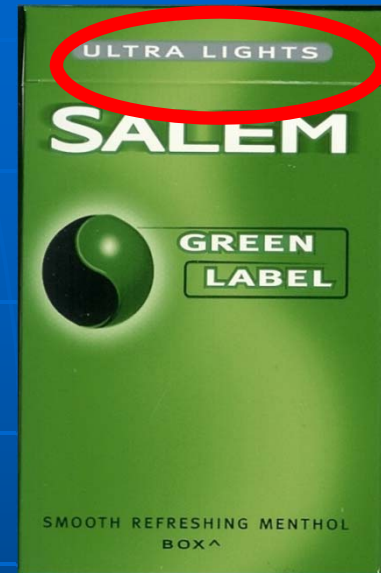


CANADA

Product Regulation

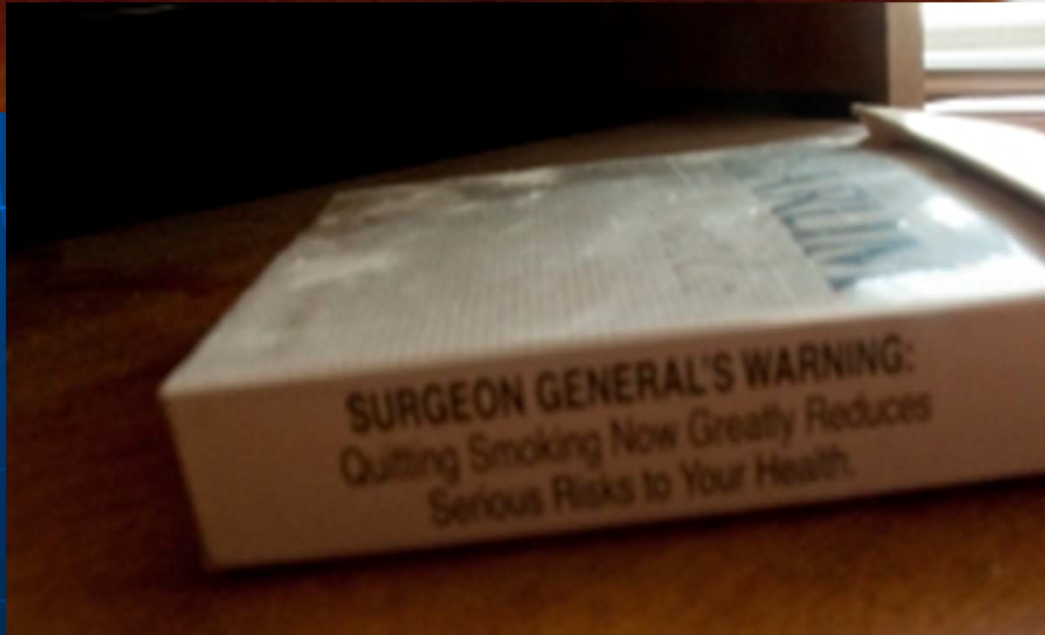
- Family Smoking and Prevention Act
 - Ban on misleading descriptors, July 2010
 - Light, low-tar, mild, etc.

“Replacement” Descriptors



Product Regulation

- 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

© U.S. HHS



**WARNING:
Tobacco smoke
causes fatal
lung disease
in nonsmokers.**

1-800-QUIT-NOW

© U.S. HHS



**WARNING: SMOKING DURING
PREGNANCY CAN HARM YOUR BABY.**

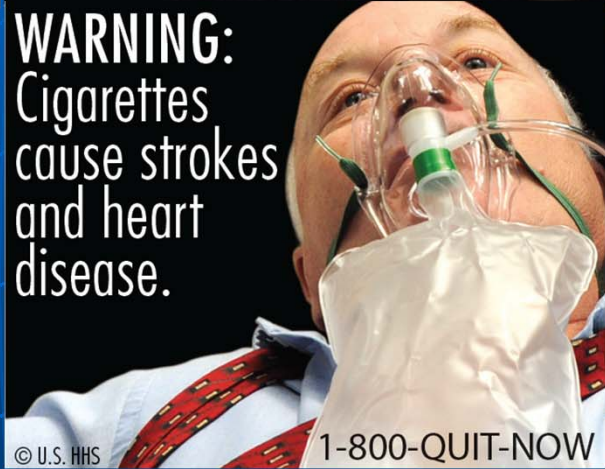
1-800-QUIT-NOW

© U.S. HHS



1-800-QUIT-NOW

© U.S. HHS



**WARNING:
Cigarettes
cause strokes
and heart
disease.**

1-800-QUIT-NOW

© U.S. HHS



1-800-QUIT-NOW

© U.S. HHS

**WARNING:
Smoking can kill you.**

**WARNING:
Cigarettes cause cancer.**



1-800-QUIT-NOW

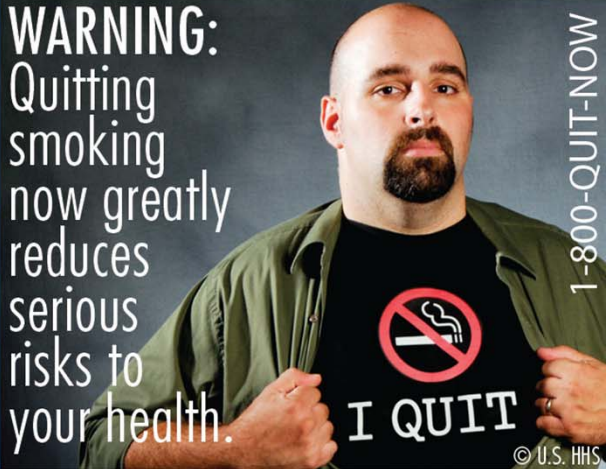
© U.S. HHS



**WARNING:
Cigarettes
are
addictive.**

1-800-QUIT-NOW

© U.S. HHS



**WARNING:
Quitting
smoking
now greatly
reduces
serious
risks to
your health.**

1-800-QUIT-NOW

I QUIT

© U.S. HHS

Warning Labels



Singapore
2004



Venezuela
2005



Thailand, 2005



Australia, 2006



Hong Kong, 2007



Belgium 2008

Source: Fong 2009; Hammond 2009



Egypt, 2008



Malaysia, 2009



Iran, 2009



Peru, 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

Product Regulation

■ 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

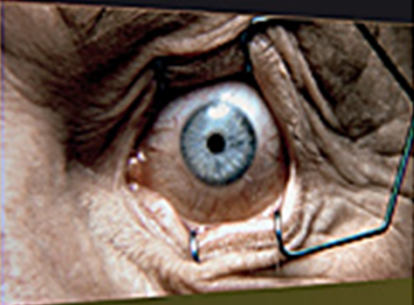
Product Regulation

- 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

**SMOKING CAUSES
BLINDNESS**



Brand
Variant

25

WARNING
The toxic chemicals in tobacco smoke damage your blood vessels, damage your body's cells and attack your immune system.

**SMOKING CAUSES
MOUTH AND THROAT
CANCER**



Mouth cancer

Brand
Variant

25

WARNING
The toxic chemicals in tobacco smoke damage your blood vessels, damage your body's cells and attack your immune system.

**DON'T LET
CHILDREN BREATHE
YOUR SMOKE**



Brand
Variant

25

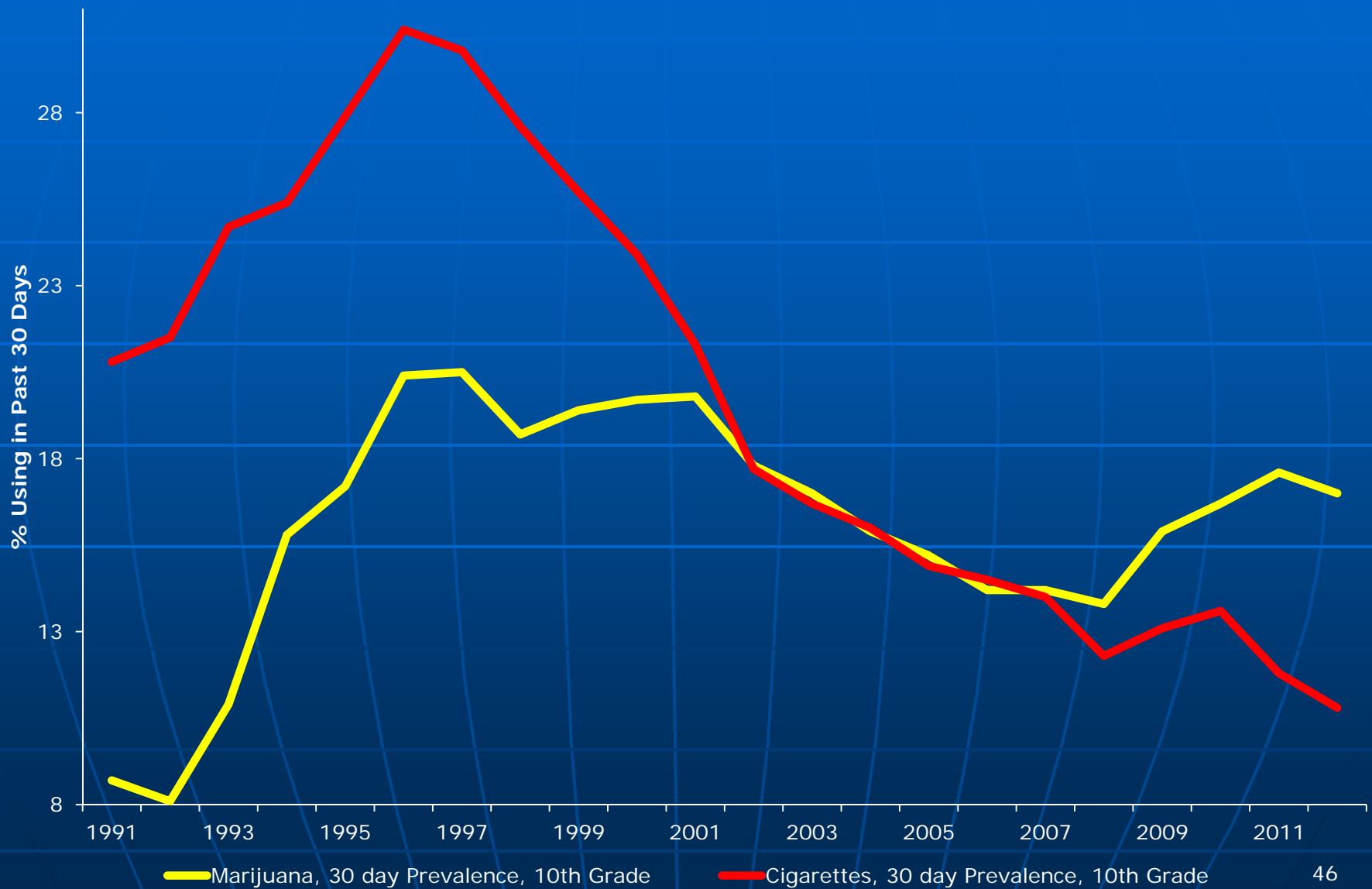
WARNING
The toxic chemicals in tobacco smoke damage your blood vessels, damage your body's cells and attack your immune system.

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)