

# PUBLIC HEALTH GRAND ROUNDS

Office of the Director

November 18, 2009



# PUBLIC HEALTH GRAND ROUNDS

Tuesday, November 17, 2009

## Office of The Director



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### Grand Rounds

The Public Health Grand Rounds is a monthly series created to further strengthen CDC's common scientific culture and foster discussion and debate on major public health issues. Each session of the Public Health Grand Rounds will focus on key issues and challenges related to a specific health topic, including cutting-edge scientific evidence and potential impact of different interventions. The sessions will also highlight how CDC is already addressing these challenges and discuss the recommendations for future research and practice.

Grand Rounds sessions are typically held on the third Thursday of every month at Roybal's Global Communications Center, Auditorium A, between 9-10 a.m. For those unable to attend, the sessions will be available on [CDC IPTV](#).

<http://intranet.cdc.gov/od/odweb/about/directorGrandRounds.htm>



# PUBLIC HEALTH GRAND ROUNDS

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## PUBLIC HEALTH GRAND ROUNDS



### Grand Rounds

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<http://www.cdc.gov/about/grand-rounds>



# PUBLIC HEALTH GRAND ROUNDS

## Access

Available on **IPTV** : <http://intra-apps.cdc.gov/itso/iptv/iptvschedule.asp>  
IPTV link also available on Grand Rounds **intranet** site:  
<http://intranet.cdc.gov/od/odweb/about/directorGrandRounds.htm>

For those outside of CDC, a broadband link is available at:  
<http://www.cdc.gov/about/grand-rounds> (Grand Rounds **internet** site)



# Continuing Education Credits

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"First they make you button your own shirt, then they make you tie your own shoes...you gotta ask yourself — where's this all heading?"

**Starting in January 2010  
Credit Hours  
will be available for:**

- Physicians (CME)**
- Non-Physicians (CME)**
- Nurses (CNE)**
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- Other Professionals (CEU)**
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- Pharmacist (CPE)**

# CME Planning Committee

- ❑ **John Iskander, MD, MPH, Chair**  
*Office of the Chief Science Officer*
- ❑ **Sharon Hall, RN, PhD**  
*Office of Workforce and Career Development*
- ❑ **Elaine Miller, RN, MPH**  
*National Center for Prevention, Detection and Control of Infectious Diseases*
- ❑ **Patricia Thomas, M(ASP), MPH, CHES**  
*Office of Workforce and Career Development*
- ❑ **Nadine Shehab, PharmD, MPH**  
*National Center for Prevention, Detection and Control of Infectious Diseases*
- ❑ **Jennifer Wright, BS, DVM, MPH**  
*National Center for Prevention, Detection and Control of Infectious Diseases*

# We Welcome Any Feedback!



For information about the Grand Rounds or to suggest future topics, please contact Dr. Tanja Popovic at [tpopovic@cdc.gov](mailto:tpopovic@cdc.gov).

If you have specific questions about the broadband link and other connectivity issues, or if interested in receiving future CDC Public Health Grand Rounds announcements, please contact Shane Joiner at [sjoiner@cdc.gov](mailto:sjoiner@cdc.gov).



# Public Health Impact of Tobacco Product and Advertising Regulation

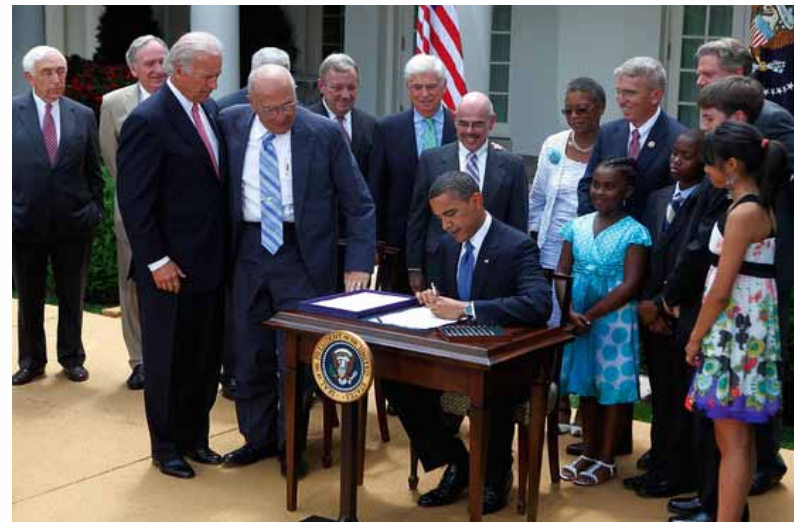


Office on Smoking and Health  
National Center for Chronic Disease Prevention and Health Promotion  
NCCDPHP



# Family Smoking Prevention and Tobacco Control Act of 2009

- ❑ On June 22, 2009, President Obama signed legislation granting the FDA the authority to regulate:
  - **CONTENT** of tobacco products
  - **MARKETING** of tobacco products
  - **SALES** of tobacco products





# Centers for Disease Control and Prevention

- ❑ **Lead federal agency for comprehensive tobacco prevention and control**
- ❑ **FY 09 Tobacco Control funding - \$106.2 M**
  - \$85 M – National Tobacco Control Program (NTCP) to support all 50 states, D.C., U.S. territories, and national organizations
- ❑ **Goals**
  - Preventing young people from starting to smoke
  - Eliminating exposure to secondhand smoke
  - Promoting quitting among young people and adults
  - Identifying and eliminating tobacco-related health disparities



# Roles for CDC in Tobacco Product Regulation

## ❑ Provide technical assistance and guidance to FDA

- Laboratory (NCEH)
- General tobacco control (OSH)

## ❑ Maintain comprehensive tobacco control programs

- Coordinate national and state regulation efforts

## ❑ Conduct post-marketing surveillance of effects of the tobacco product regulation





# Outline

- ❑ **Terry Pechacek, PhD**, Office on Smoking and Health
  - *Overview of Tobacco Control in the United States*
  
- ❑ **CAPT Matthew McKenna, MD, MPH**, Office on Smoking and Health
  - *International Advances in Tobacco Control through Policy and Regulation*
  
- ❑ **CAPT David Ashley, PhD**, National Center for Environmental Health
  - *Product Regulation – Does it Fit into Tobacco Control?*
  
- ❑ **Lawrence Deyton, MD, MSPH**, Food and Drug Administration
  - *Overview of the Family Smoking Prevention and Tobacco Control Act*

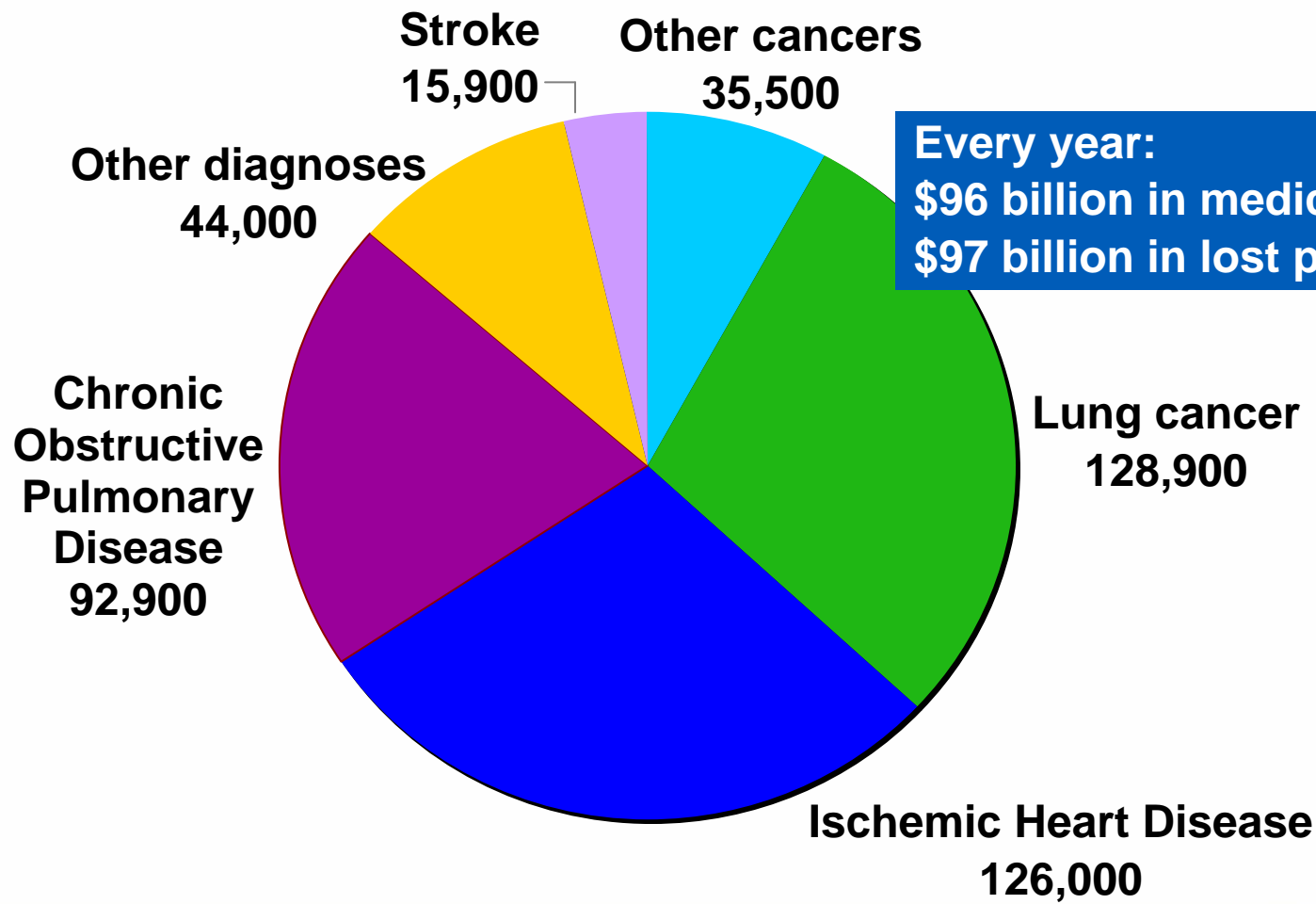


# OVERVIEW OF TOBACCO CONTROL IN THE UNITED STATES



**Terry F. Pechacek, PhD**  
***Associate Director for Science***  
**Office on Smoking and Health, NCCDPHP**

# About 443,000 U.S. Deaths Per Year Attributable to Cigarette Smoking

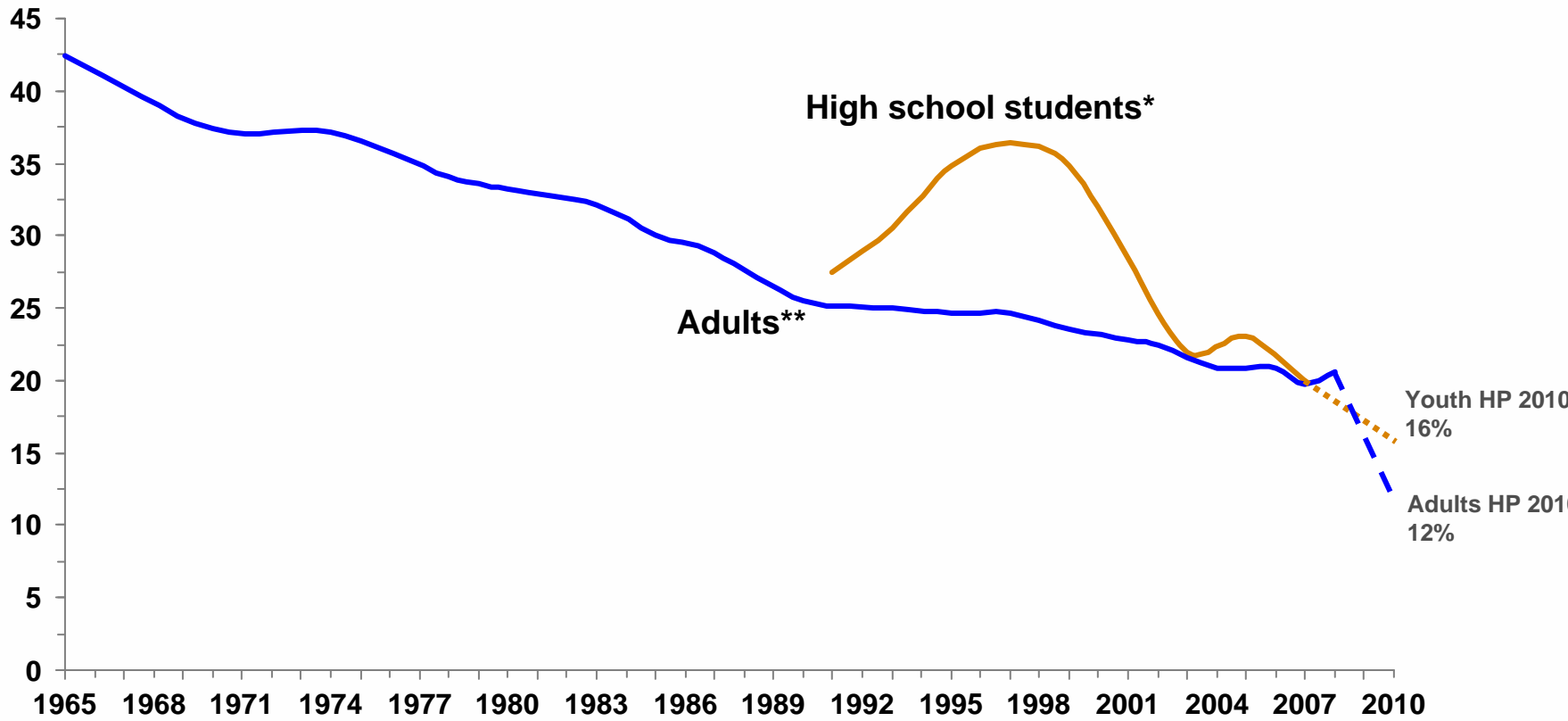


\*Average number of deaths, 2000-2004.

Source: *MMWR* 2008;57(45):1226-1228.



# Trends in Current Cigarette Smoking by High School Students and Adults—United States, 1965-2007



\*High school students who smoked on 1 >/ of the 30 days preceding the survey--United States, CDC. Youth Risk Behavior Survey, 1991-2007.

\*\* Total population adults who were current cigarette smokers, National Health Interview Surveys, 1965-2006.



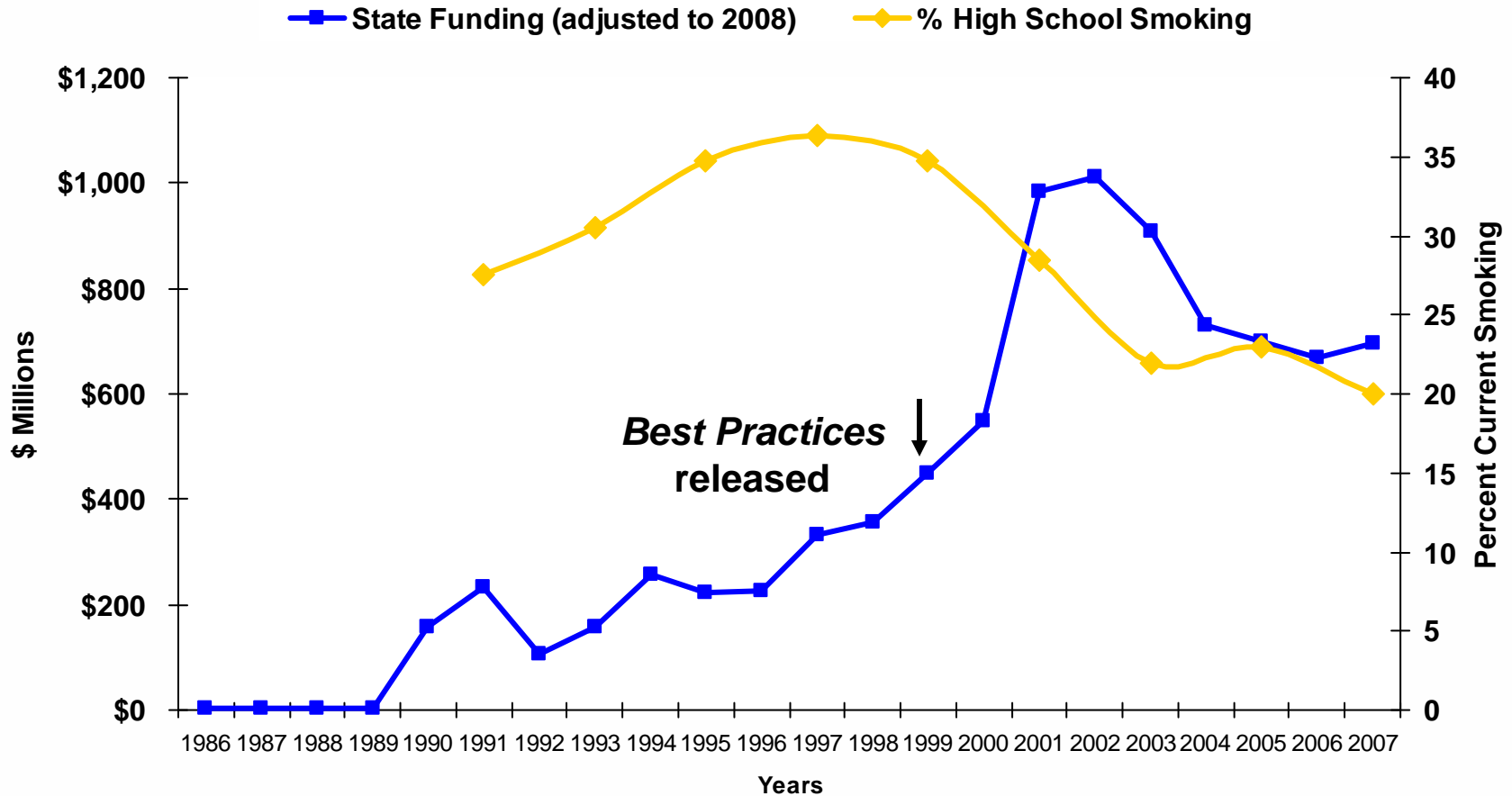
# Evidence-Based Interventions

- ❑ Sustained funding of comprehensive programs
- ❑ Excise tax increases
- ❑ 100% smoke-free policies
- ❑ Comprehensive ad restrictions
- ❑ Aggressive media campaigns
- ❑ Cessation access





# Total Funding for State Programs Adjusted to FY2008 Dollars

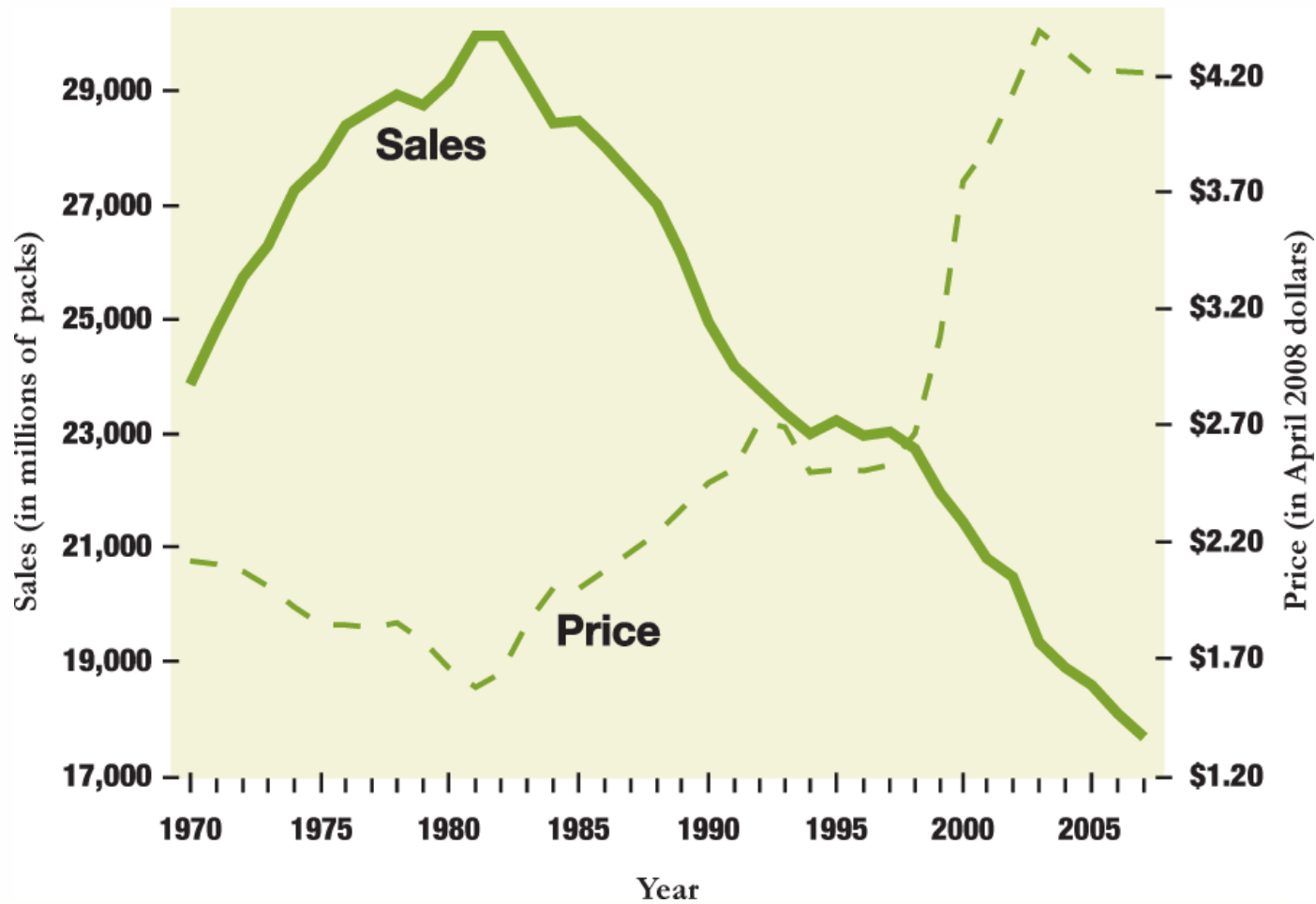


Source: Project ImpactTEEN; CDC/Office on Smoking and Health; Campaign for Tobacco Free Kids; Research Triangle Institute; University of Illinois at Chicago; University at Buffalo, State University of New York  
 \*High school students who smoked on 1 >/ of the 30 days preceding the survey--United States, CDC. Youth Risk Behavior Survey, 1993-2007.





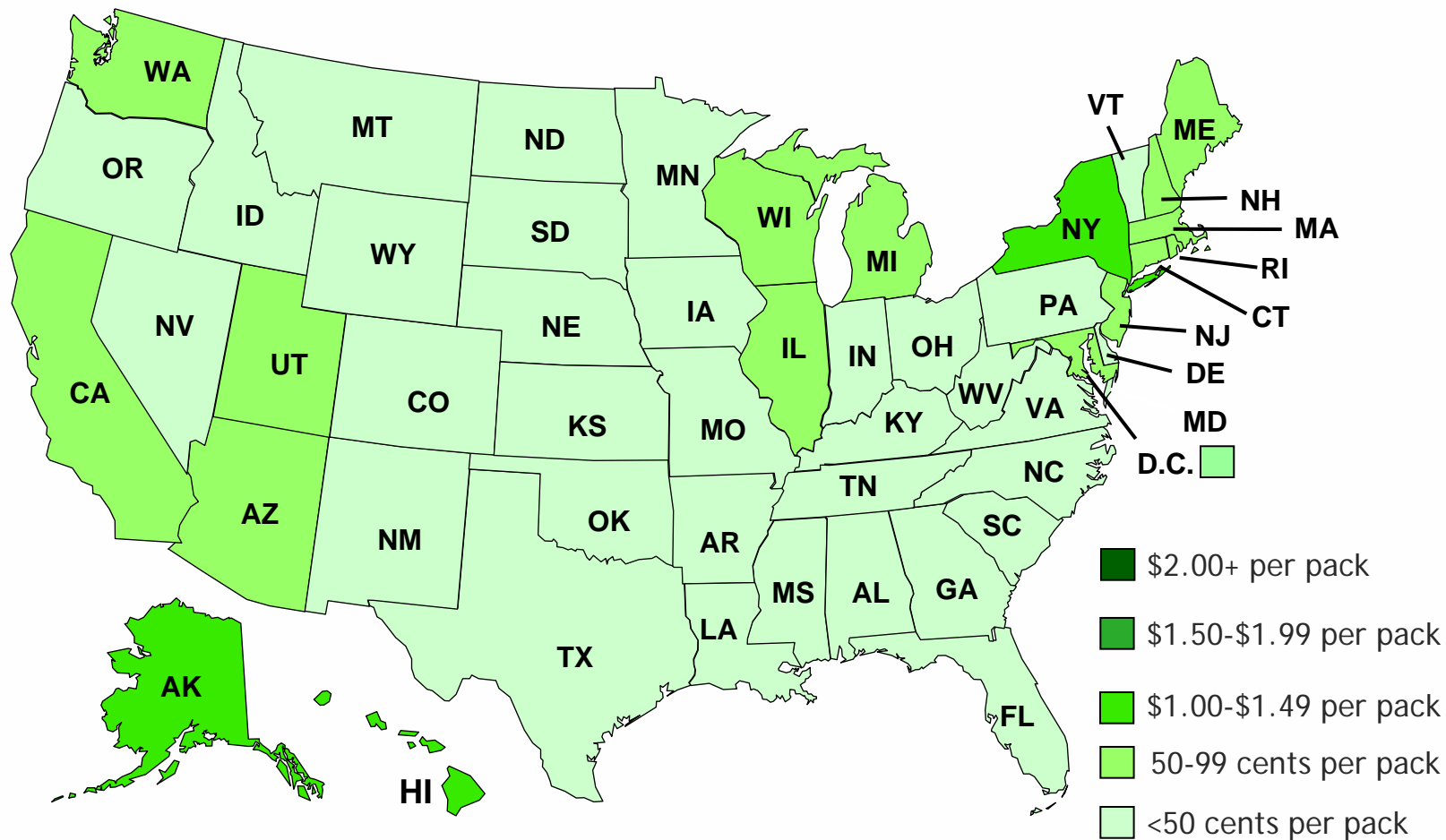
# Cigarette Sales and Cigarette Prices United States, 1970-2007



Source: ImpacTeen Chartbook: Cigarette Smoking Prevalence and Policies in the 50 States.



# State Cigarette Excise Tax Rates - 2000

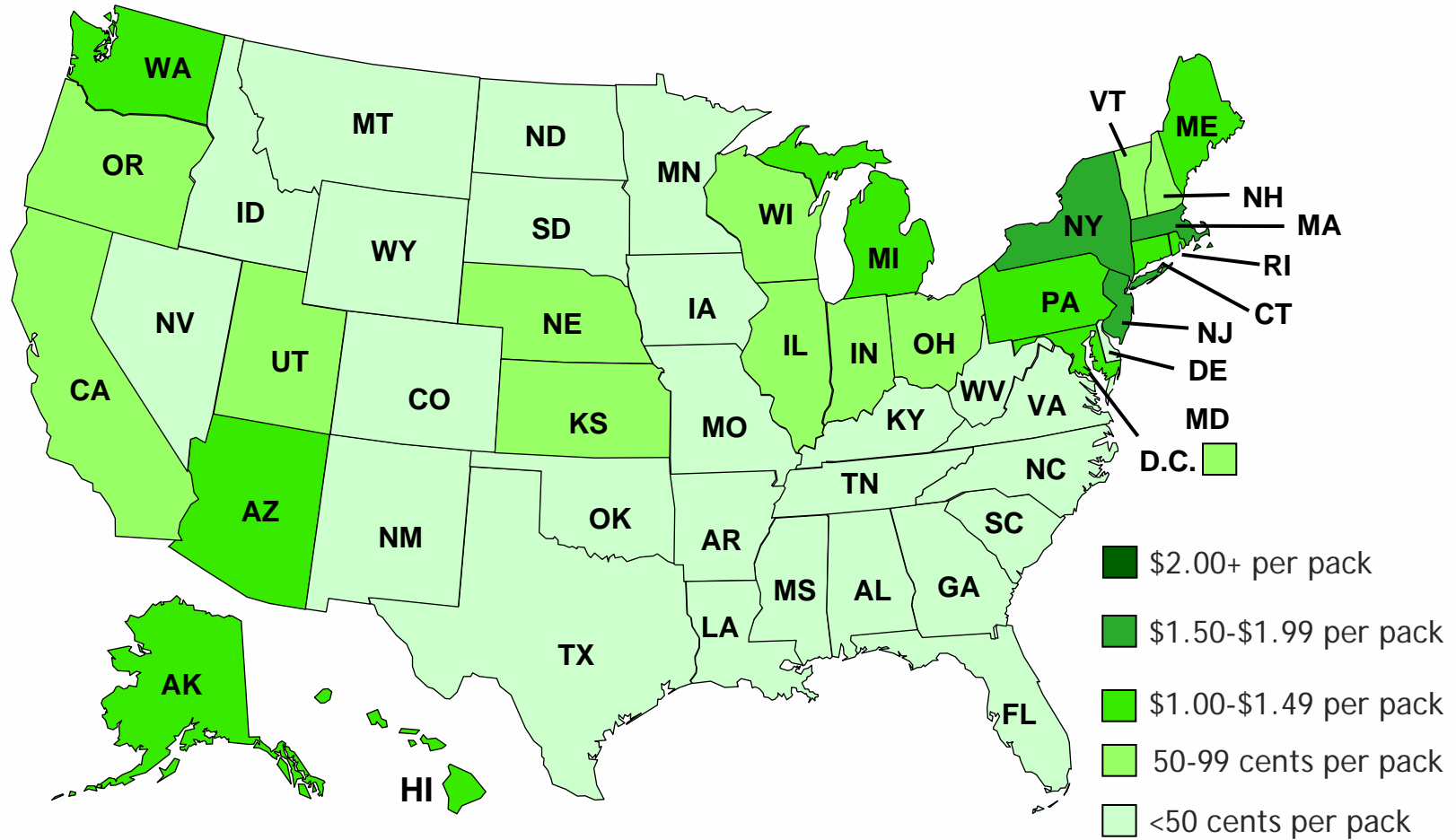


Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.





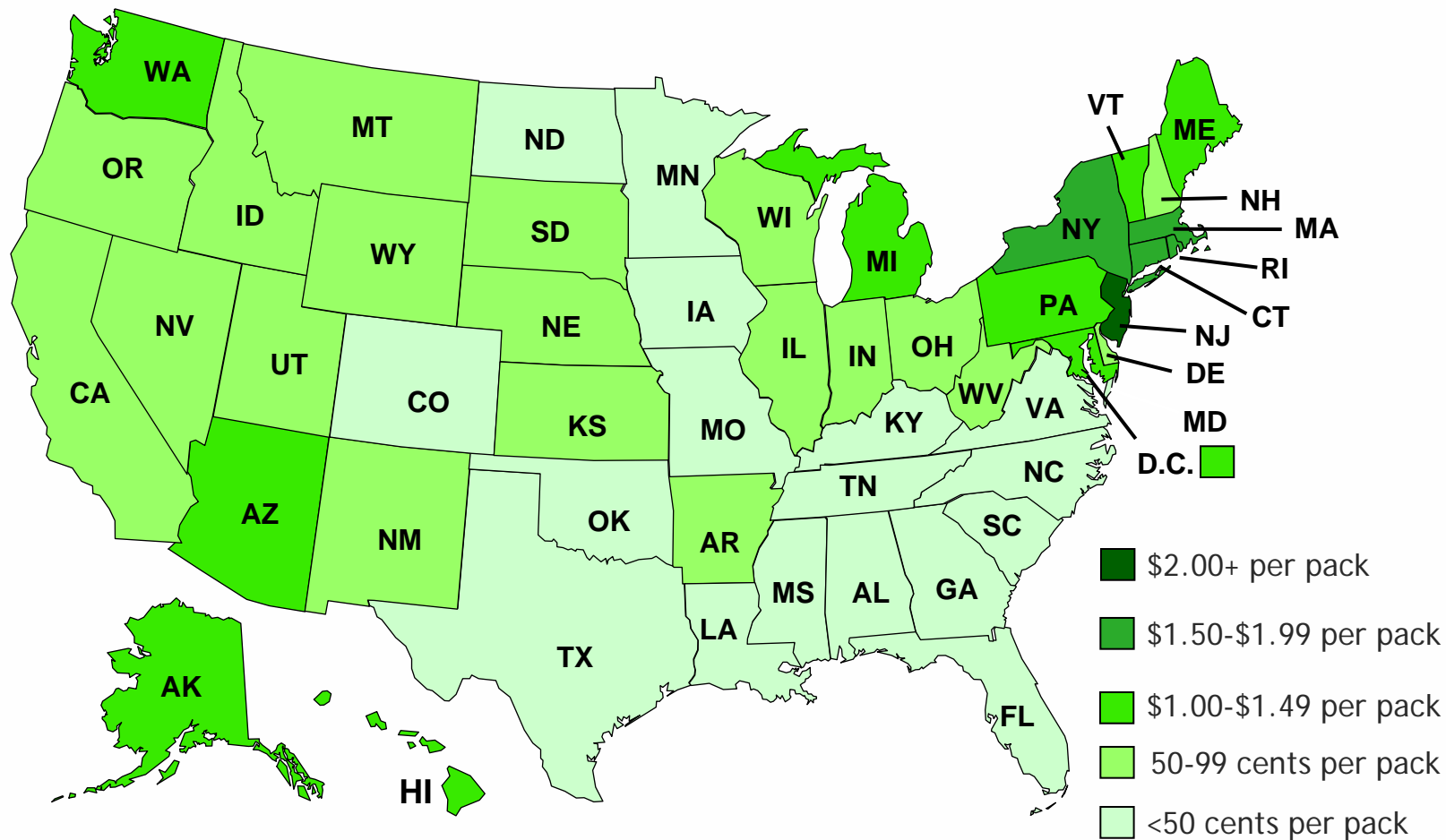
# State Cigarette Excise Tax Rates - 2002



Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.



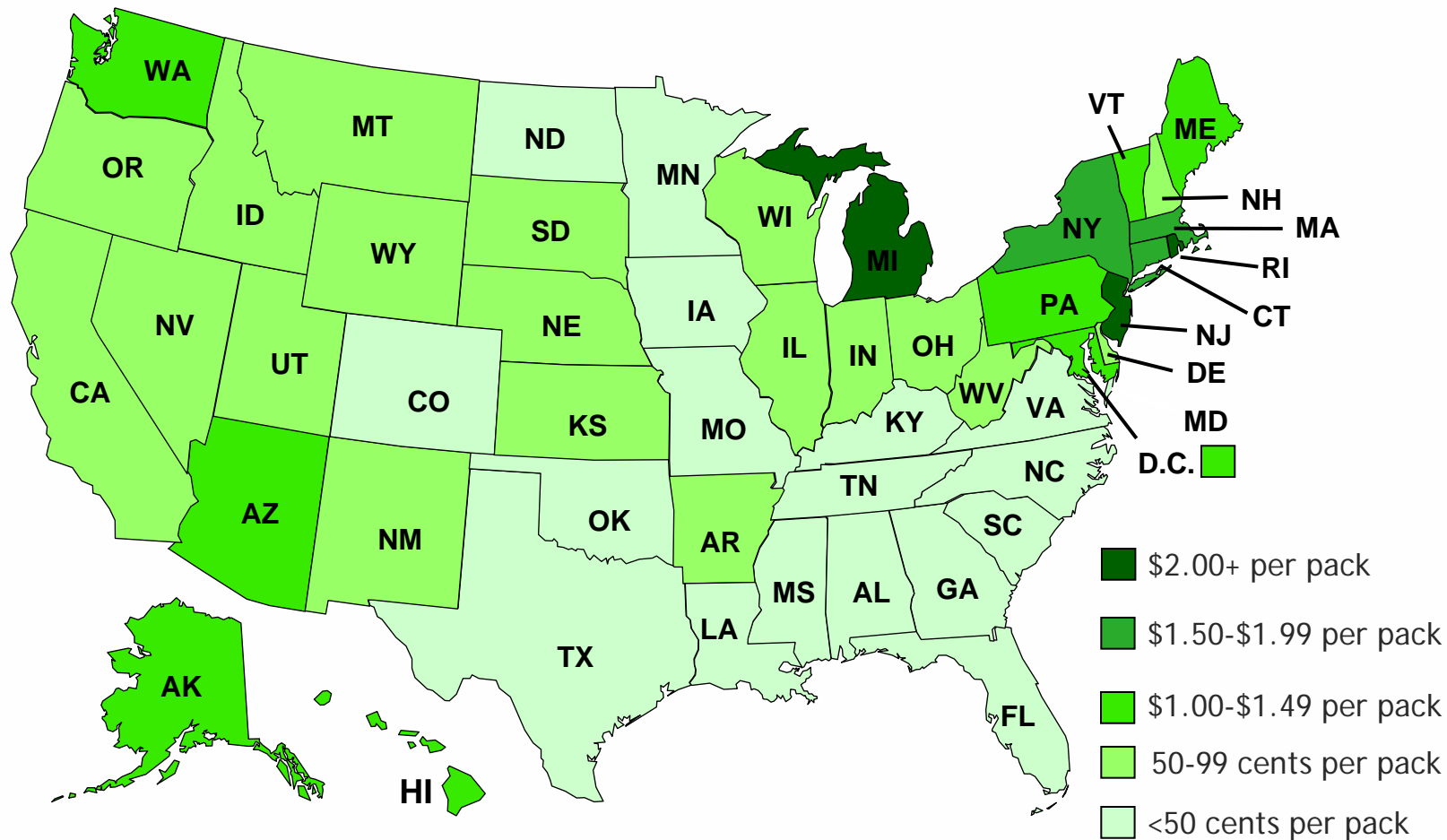
# State Cigarette Excise Tax Rates - 2003



Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.



# State Cigarette Excise Tax Rates - 2004

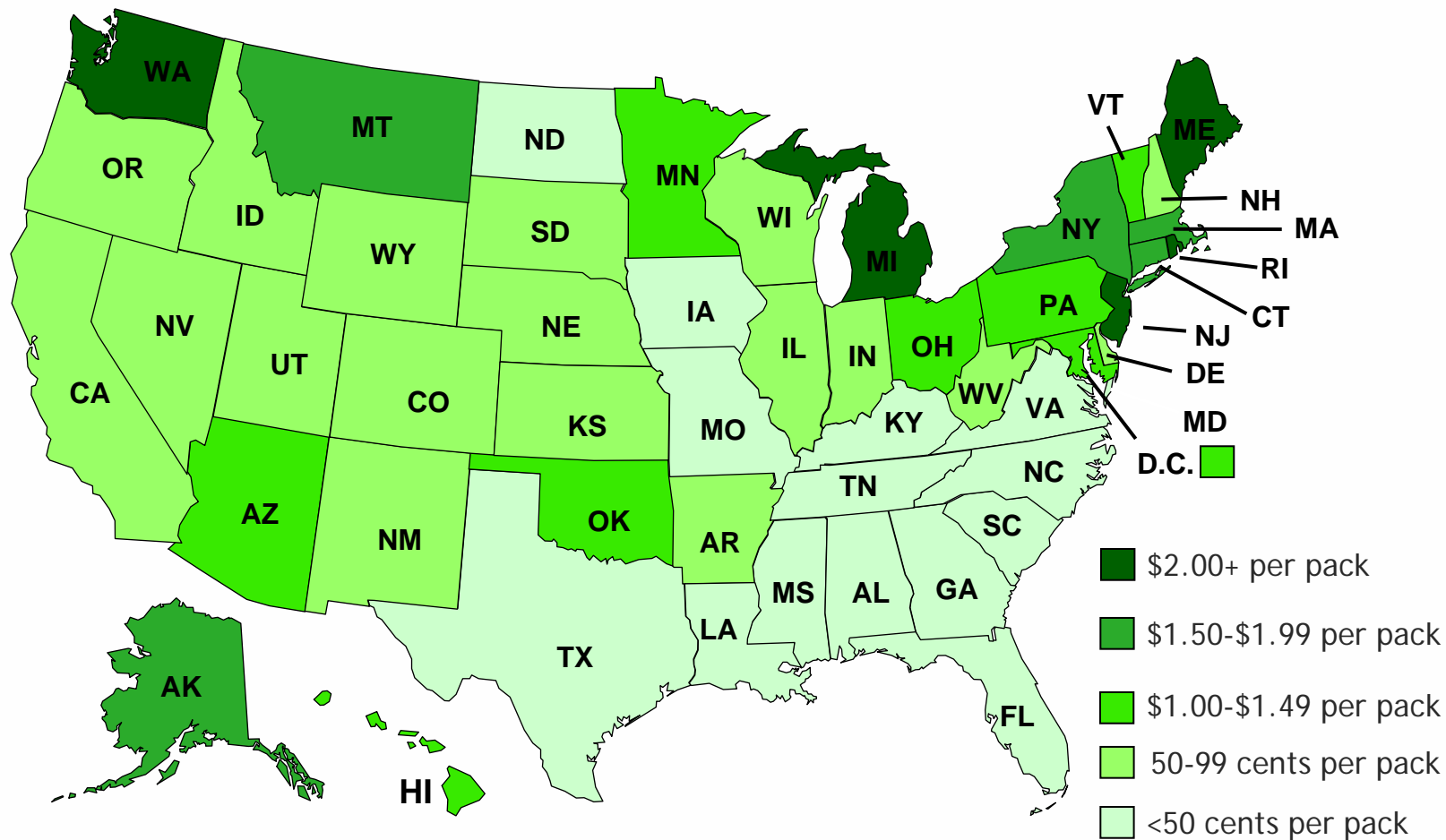


Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.





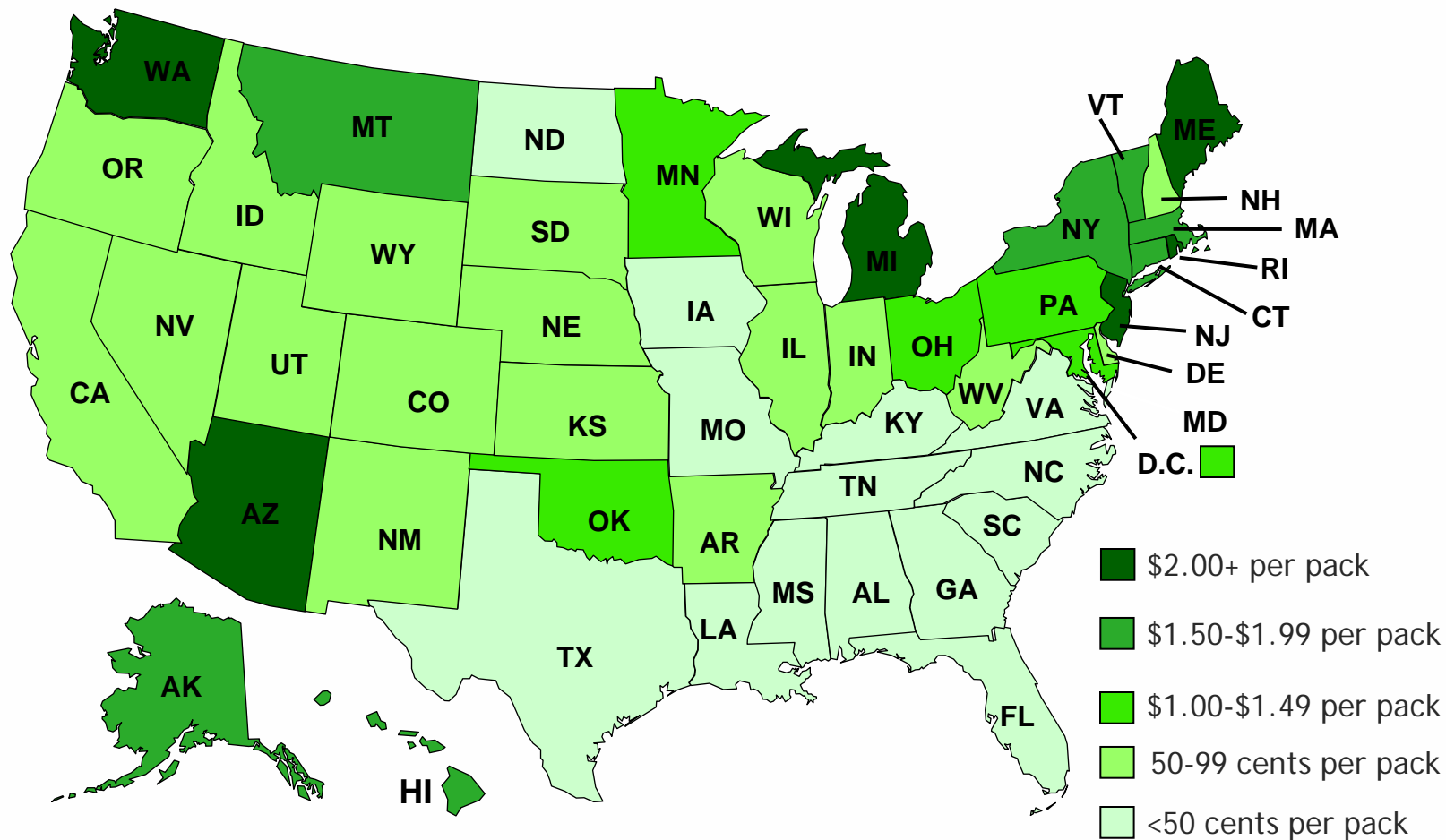
# State Cigarette Excise Tax Rates - 2005



Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.



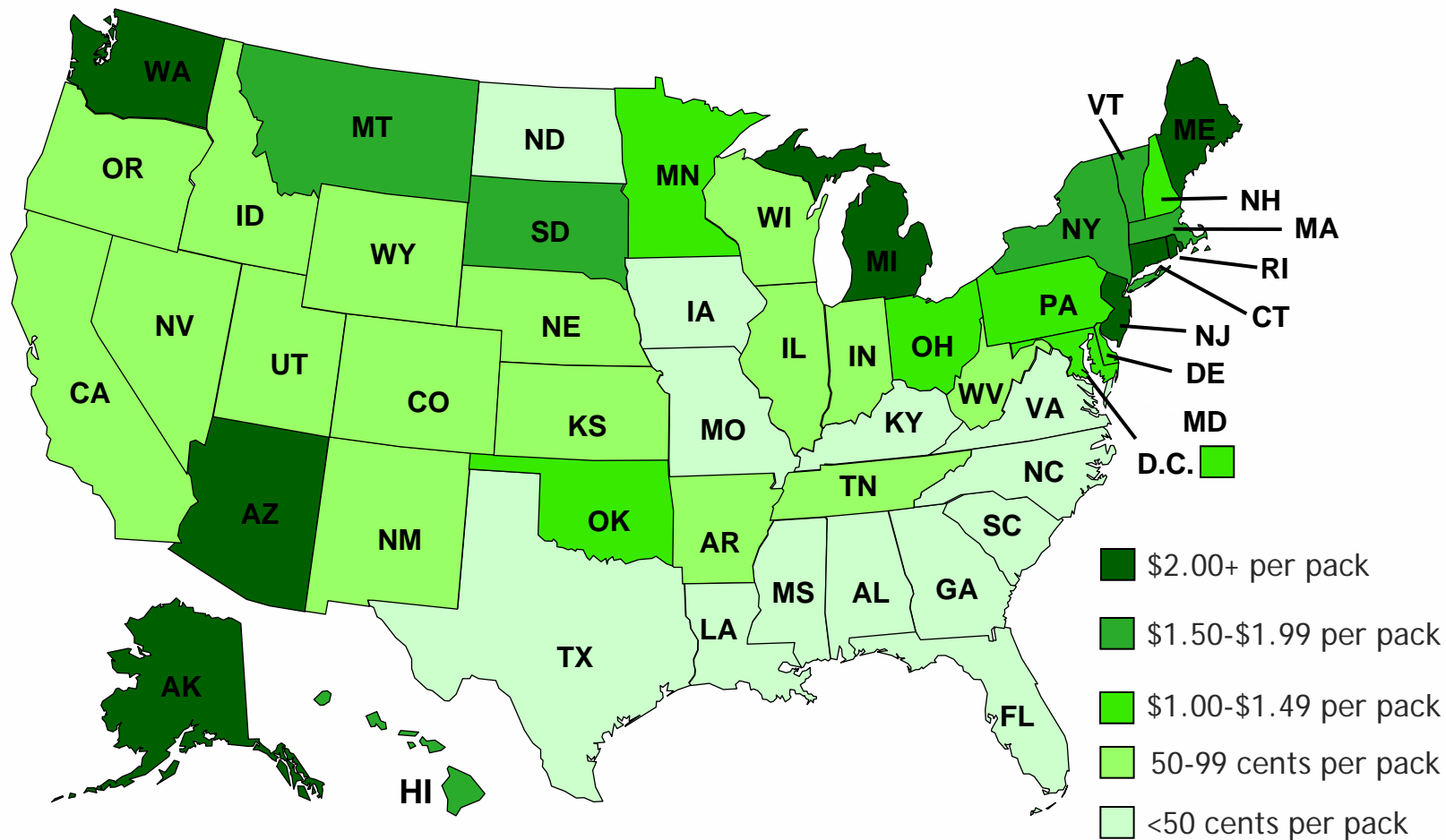
# State Cigarette Excise Tax Rates - 2006



Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.



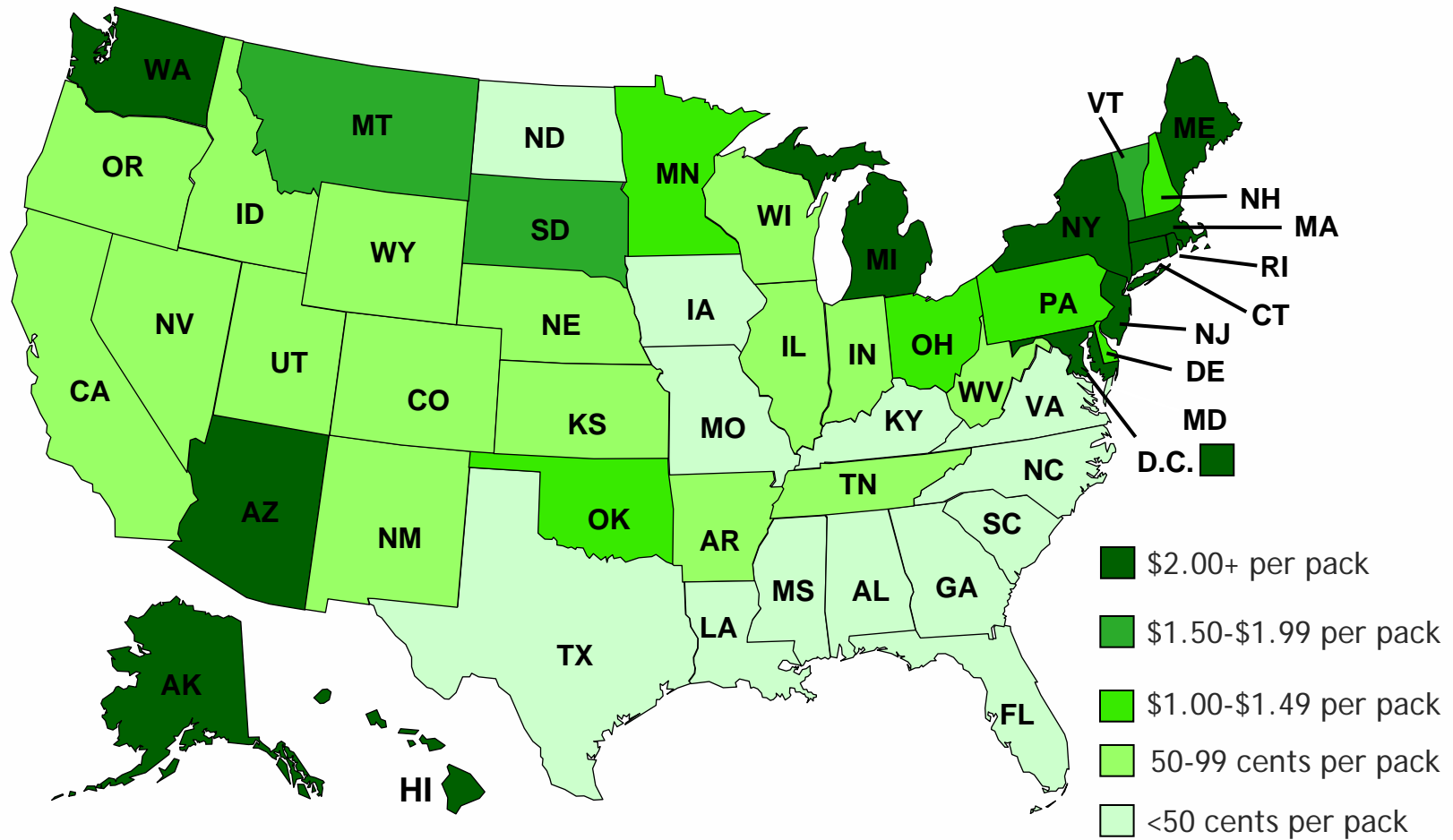
# State Cigarette Excise Tax Rates - 2007



Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.



# State Cigarette Excise Tax Rates - 2008

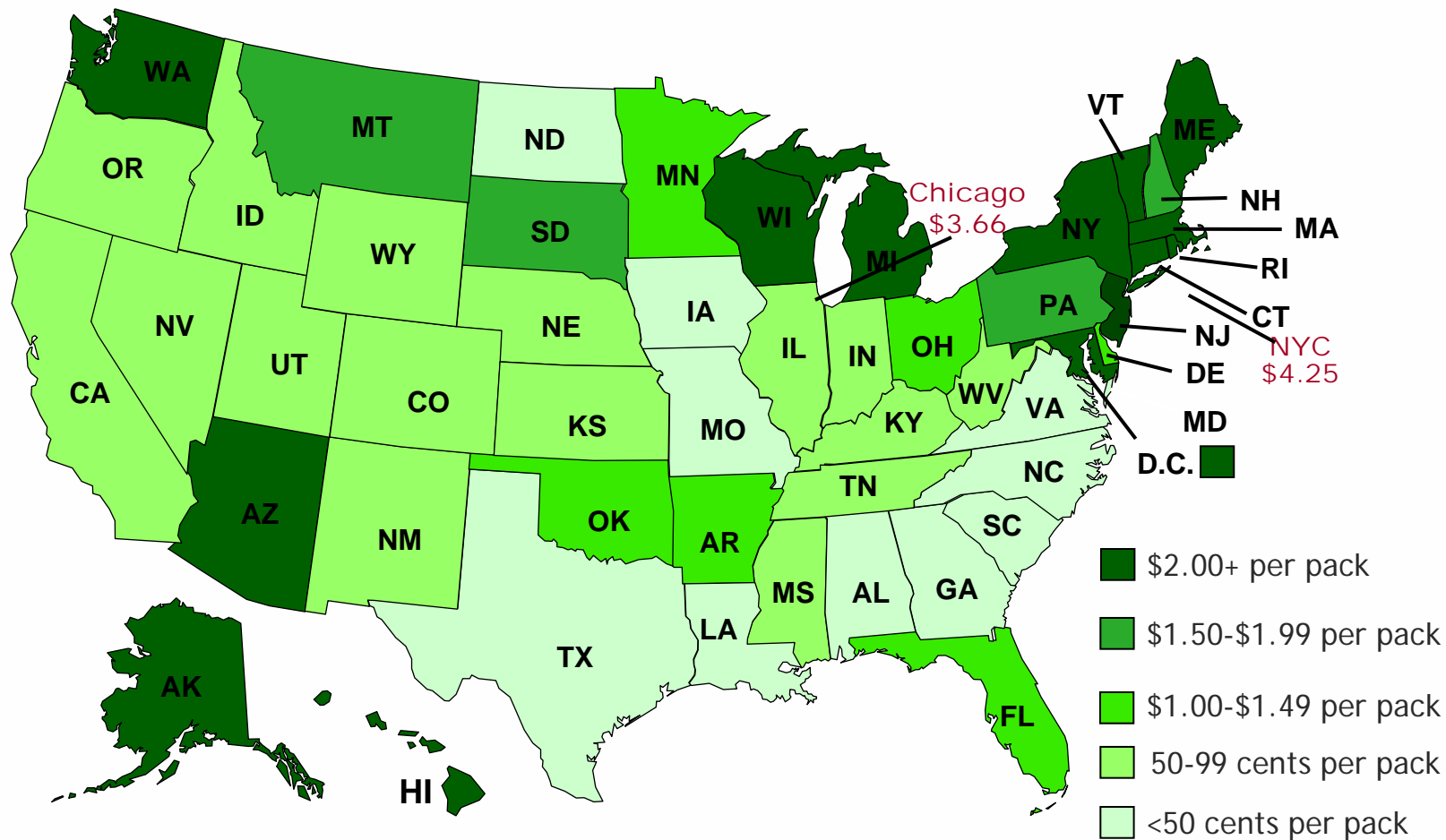


Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.





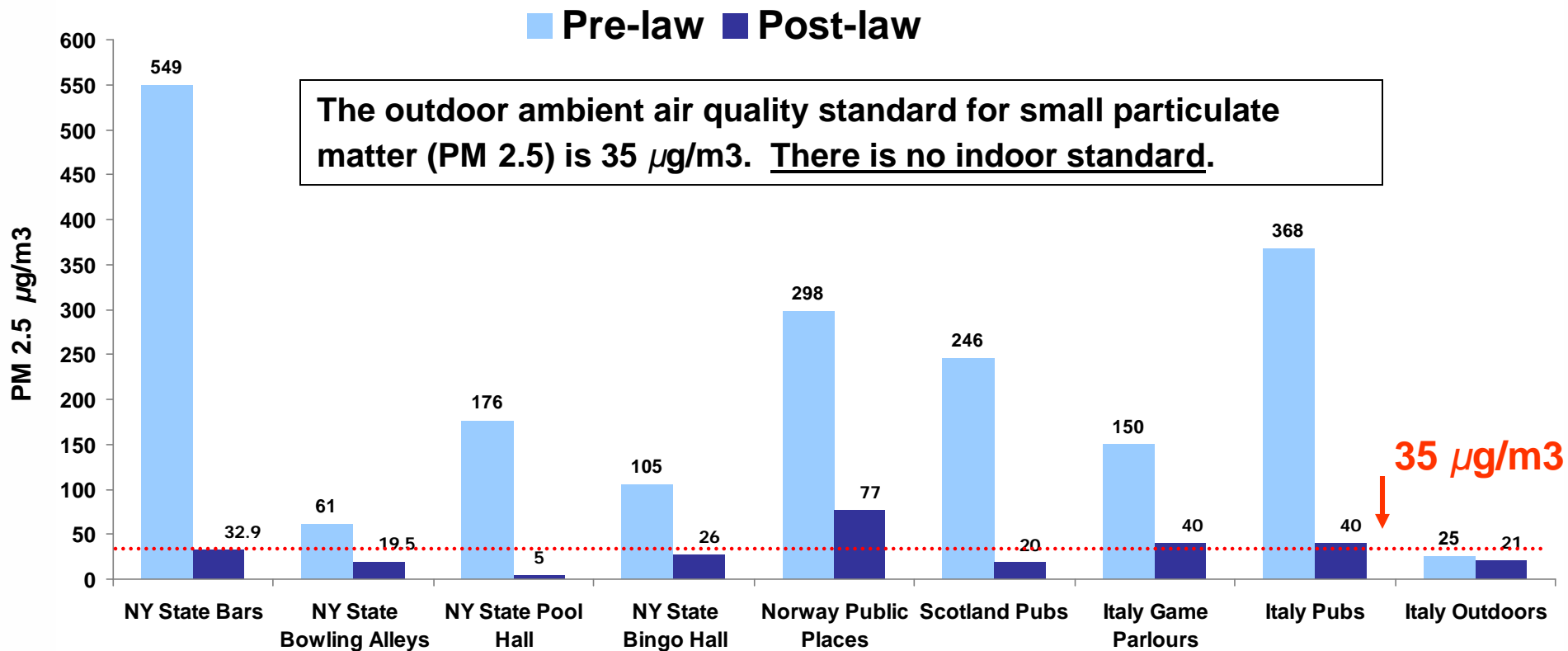
# State Cigarette Excise Tax Rates - 2009



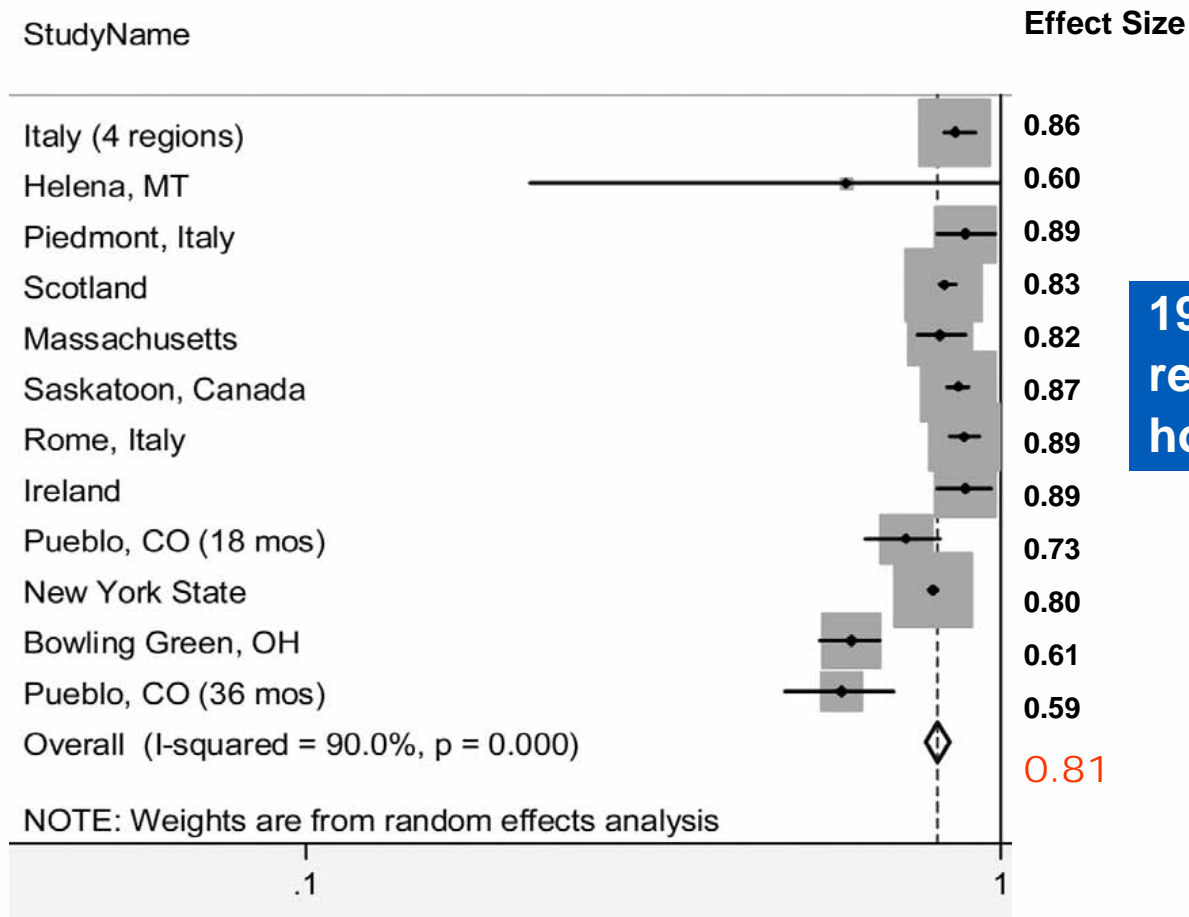
Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.



# Indoor Air Quality Before and After Implementing a Smoke-Free Law



# Smoke-Free Policies Reduce Hospitalizations for Acute Myocardial Infarctions



**19% average  
reduction in  
hospitalizations**



# Institute of Medicine Report: Secondhand Smoke Exposure & Cardiovascular Effects

## □ Purpose

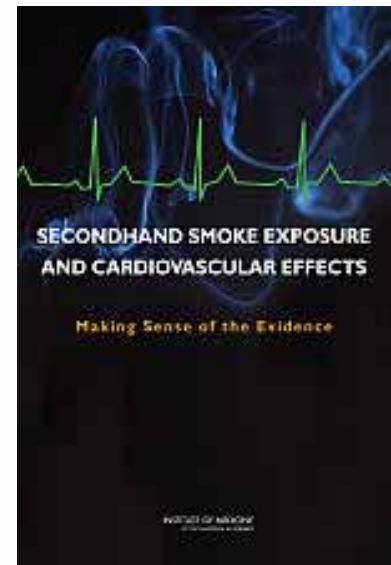
- To assess the relationship between secondhand smoke exposure and acute coronary events

## □ Conclusions

- Secondhand smoke causes heart attacks
- Even brief secondhand smoke exposure could trigger a heart attack
- Smoke-free laws prevent heart attacks and save lives

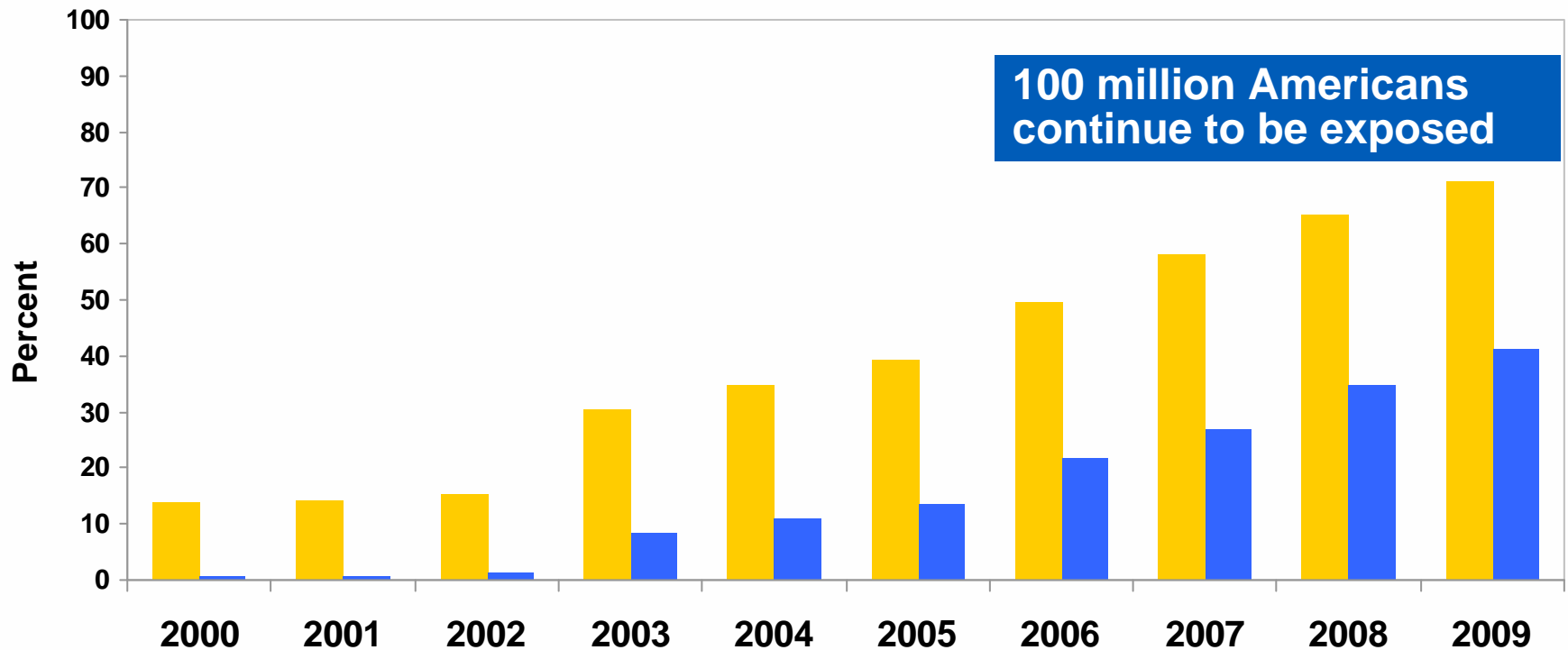
## □ Concurred with 2006 Surgeon General's Report

- Secondhand smoke exposure increases the risk of coronary heart disease by 25-30 %



# Proportion of U.S. Population Covered by Local and State Smoke-Free Laws, 2000-2009

- Workplaces and/or Restaurants and/or Bars
- Workplaces and Restaurants and Bars



Population figures are as of December 31 of each given year, and October for 2009. All population figures are from the United States Census. Source: American Nonsmokers' Rights Foundation.



# Aggressive Media Campaigns

## □ Media campaigns

- Reduce youth initiation
- Encourage cessation
- Increase negative attitudes toward tobacco use





# The Impact of Cessation

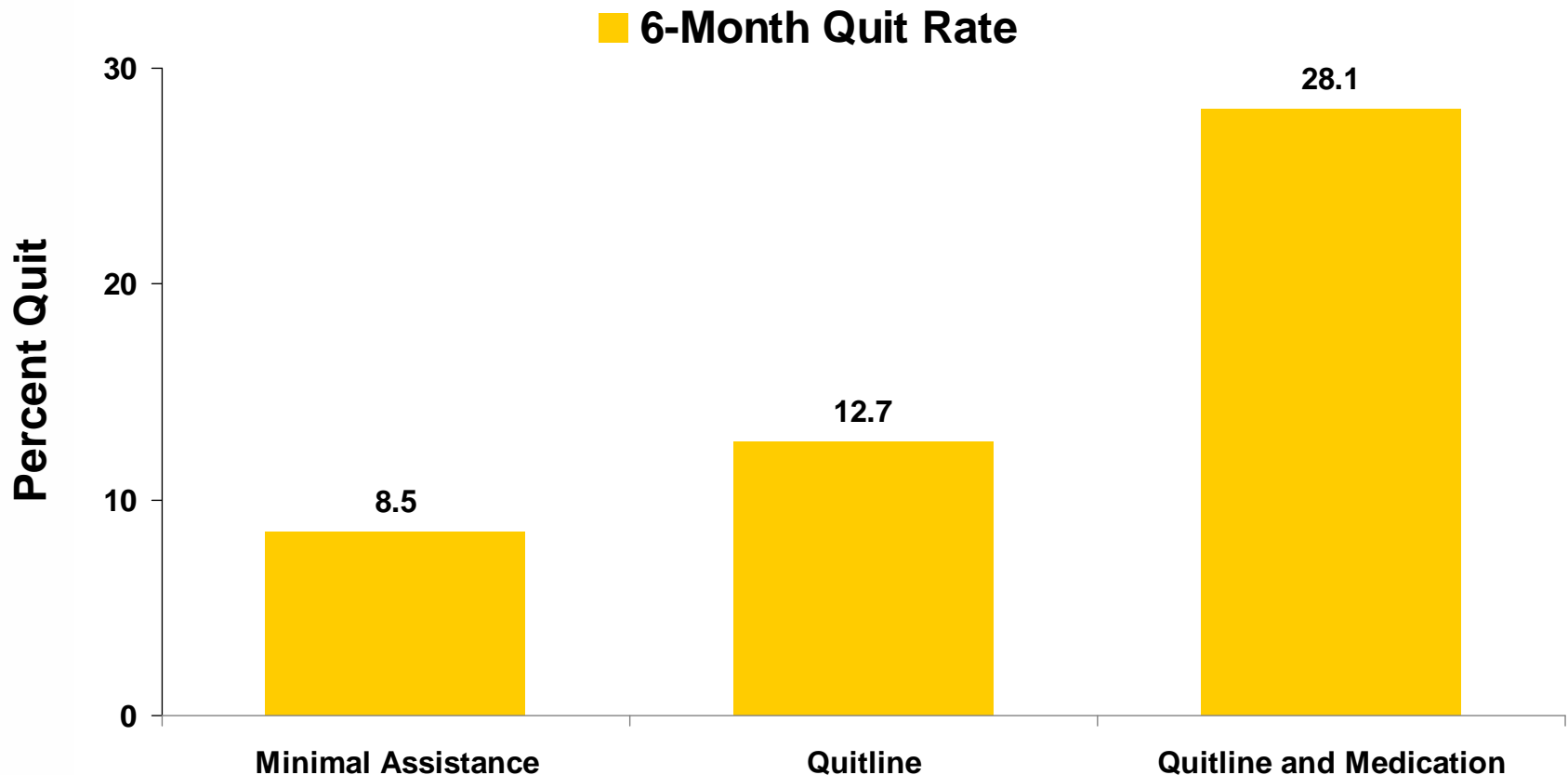
## □ Presently: 46 million U.S. smokers

- 70% of smokers want to quit
- 40% try to quit each year
- Only 2% call state or national quitlines

## □ Tobacco cessation works best when combined with

- Significant tax and price increases
- Comprehensive smoke-free policies
- Advertising, promotion and sponsorship bans
- Aggressive counter-advertising

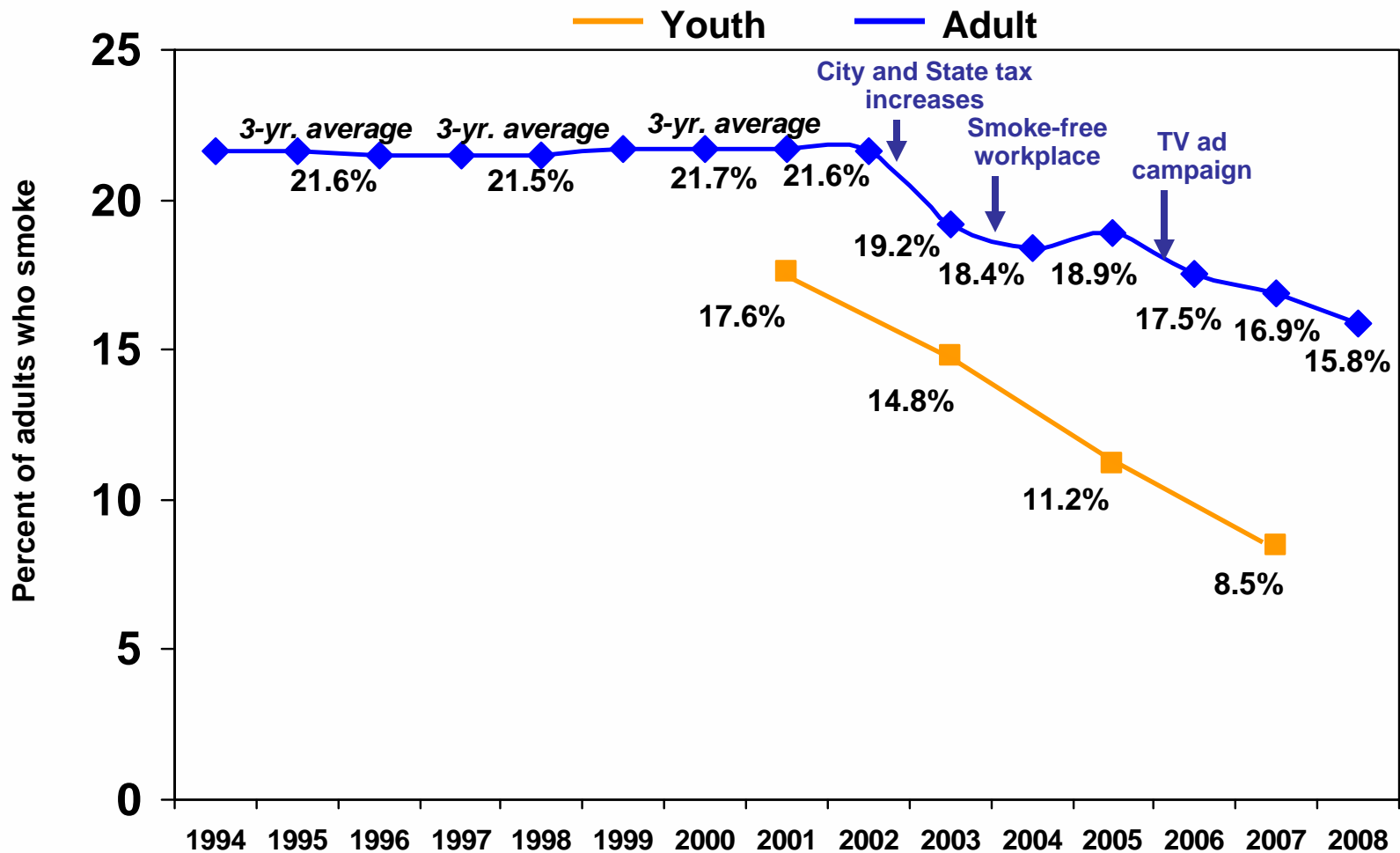
# Quitline Counseling Alone or with Medication Significantly Increases 6-Month Abstinence Rates



Source: Clinical Practice Guideline Meta-Analysis Results. *Treating tobacco use and dependence: 2008 update*. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service; 2008 May.



# Adult and Youth Smoking Prevalence in New York City



Source: CDC. Decline in Smoking Prevalence -- New York City, 2002—2006. MMWR. 2007. 56(24);604-608; and New York City Department of Health and Mental Hygiene.

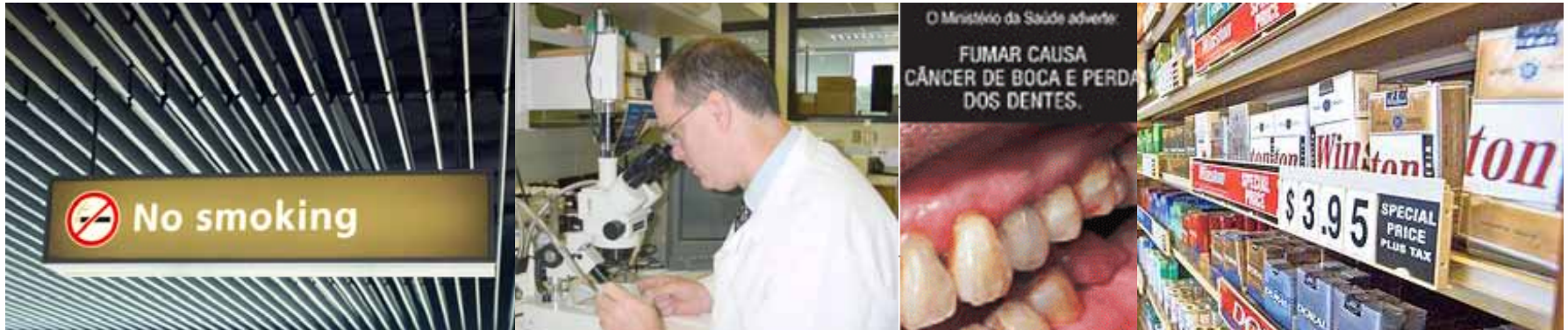


# Opportunities Moving Forward



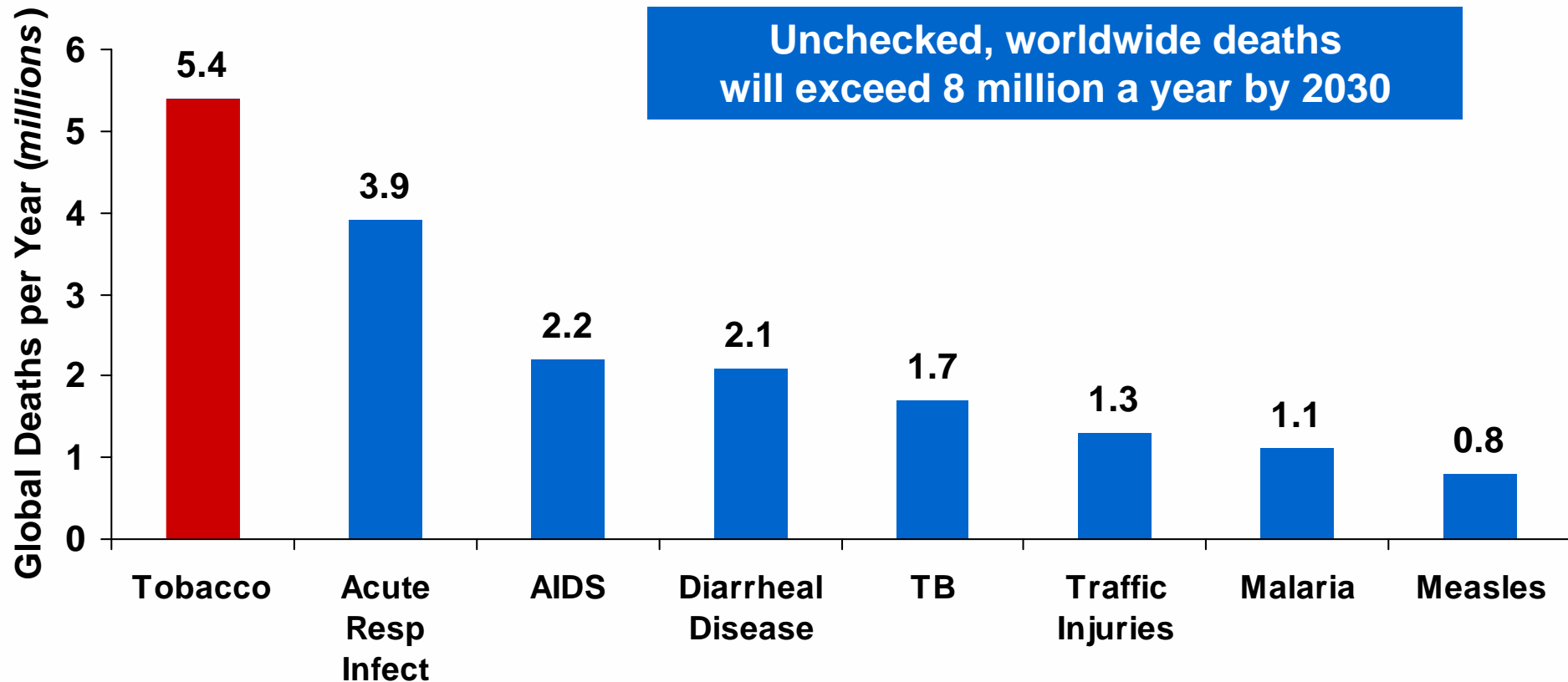


# INTERNATIONAL ADVANCES IN TOBACCO CONTROL THROUGH POLICY AND REGULATION



**CAPT Matthew T. McKenna, MD, MPH**  
*Acting Director*  
**Office on Smoking and Health, NCCDPHP**

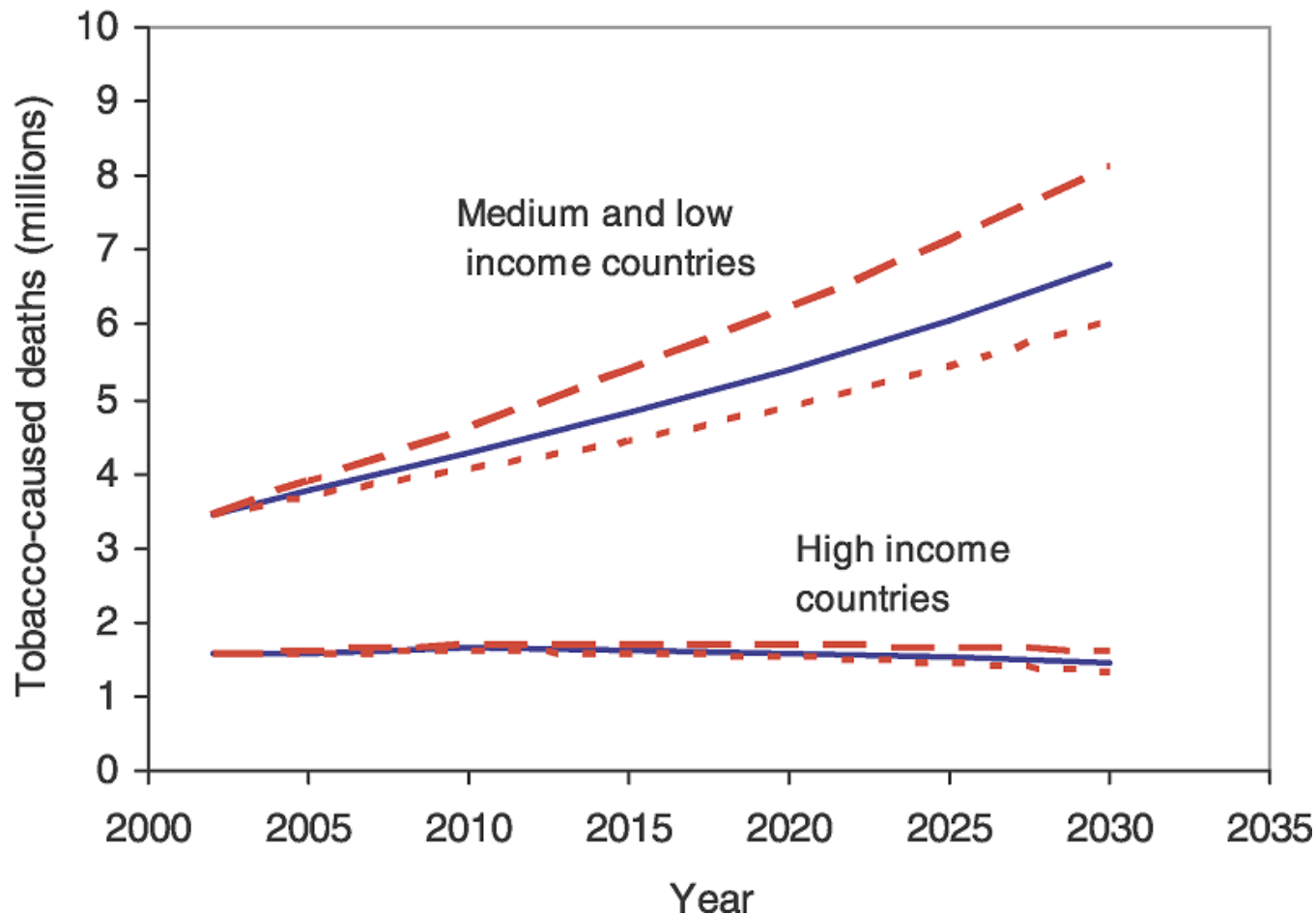
# Tobacco Is Now the World's Leading Preventable Cause of Death



Source: World Health Organization



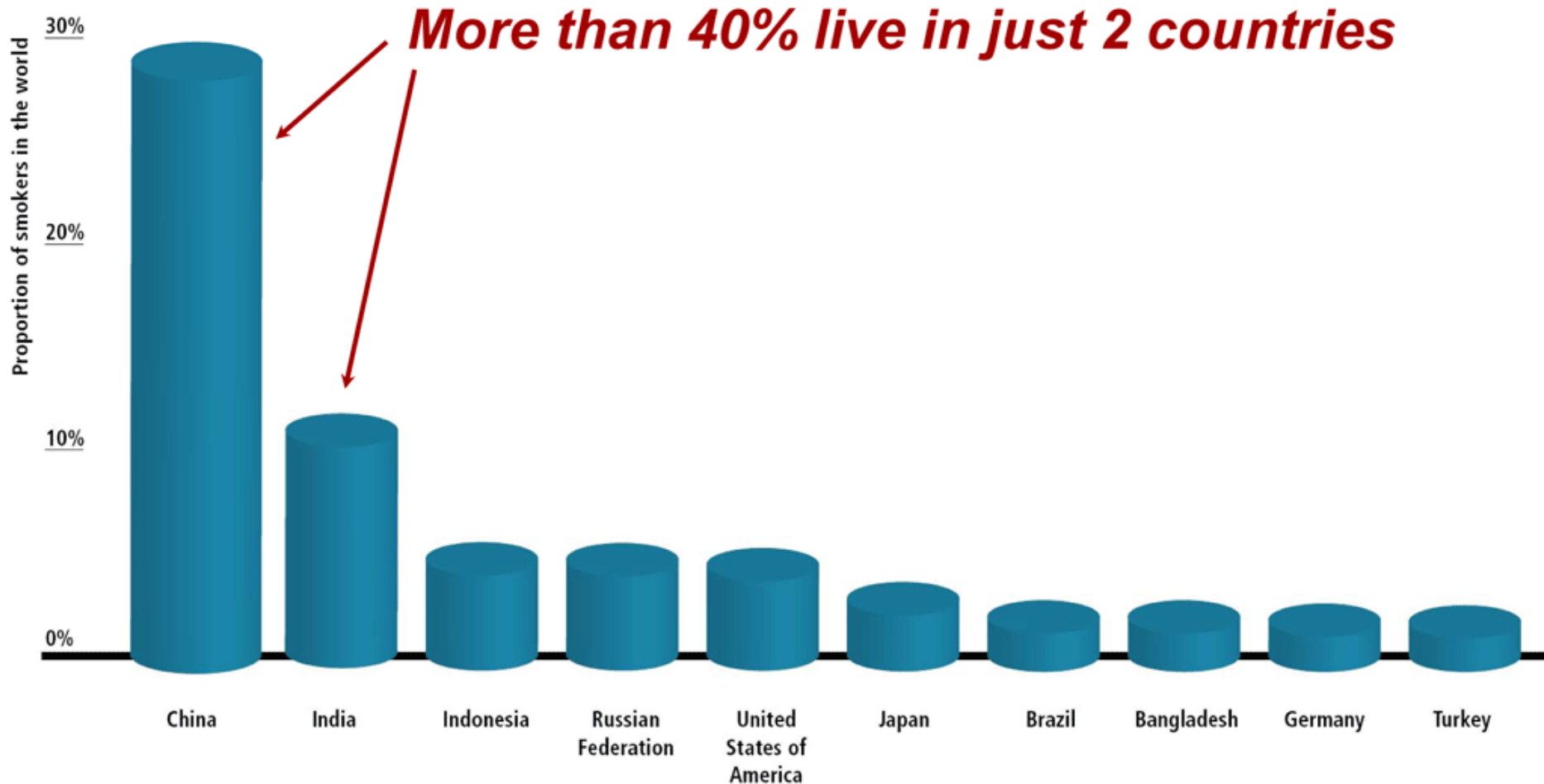
# Projected Deaths Attributable to Tobacco Unless Effective Programs Are Implemented



Source: Mathers and Loncar, Plos Med, 2006; 3: 2011-2030.



# Nearly 2/3 of the World's Smokers Live in Just 10 Countries



Source: WHO MPOWER Report 2008.





# There ARE Effective and Proven Strategies

- ❑ **100,000,000 global deaths can be prevented by the end of the century through a group of policy and regulatory interventions**
- ❑ **This number of lives saved is possible through a modest prevalence decline (from 25% to 20%), using the assumption that 1/3 of users will die from smoking-related diseases**



# mpower

**M**onitor tobacco use  
and prevention policies

**P**rotect people from  
tobacco smoke

**O**ffer help to quit  
tobacco use

**W**arn about the dangers  
of tobacco

**E**nforce bans on tobacco  
advertising, promotion and sponsorship

**R**aise taxes on tobacco

# Smoke-Free Areas



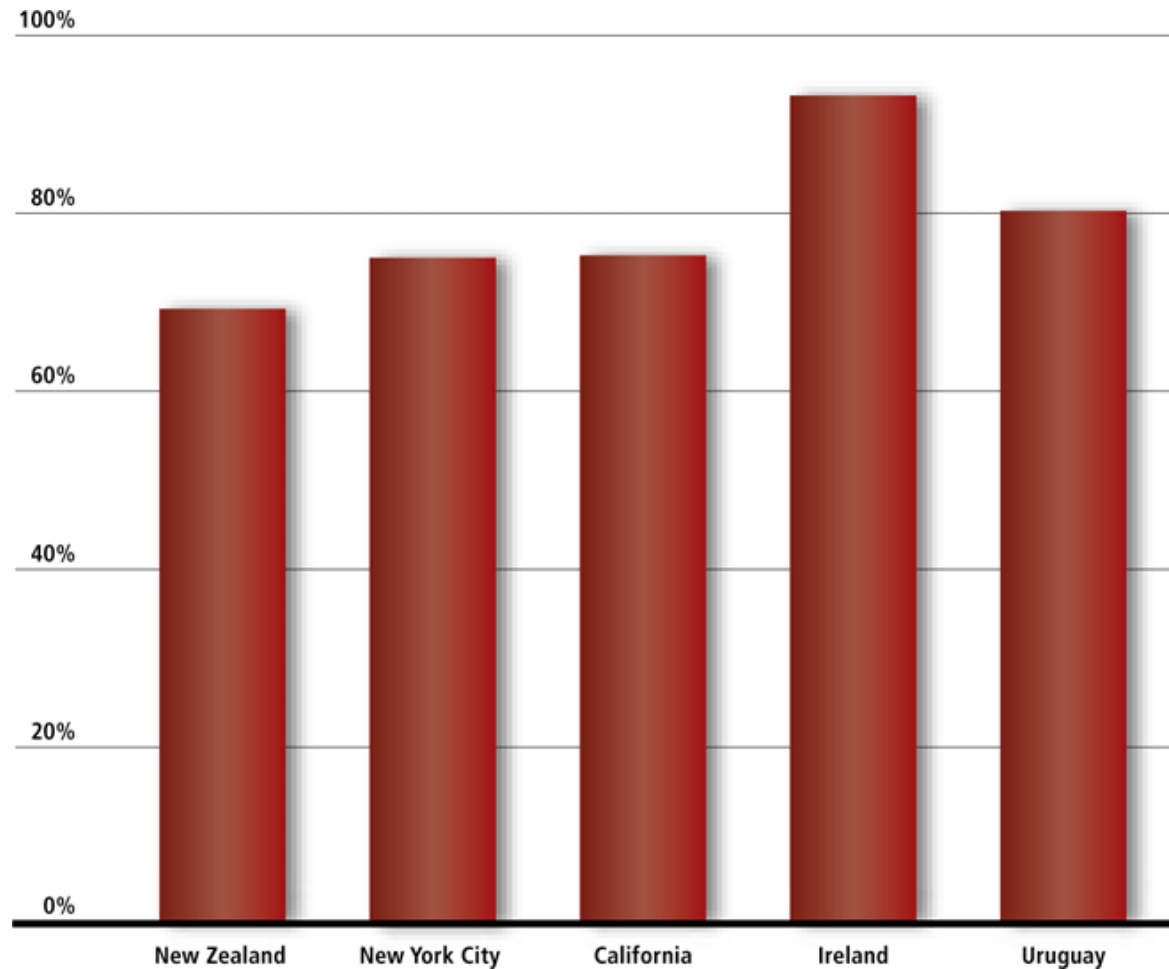
Smoke-Free Areas, 2008

- X Complete ban\*
- X Strong ban\*\*
- X Moderate ban\*\*\*
- X Minimal ban\*\*\*\*
- X Local legislation\*\*\*\*\*
- X No ban\*\*\*\*\*
- X No Data
- X Countries without smoking restrictions in educational facilities, 2007

Source: The Tobacco Atlas, 3<sup>rd</sup> Edition, 2008.



# Public Support for Comprehensive Smoking Bans in Bars and Restaurants after Implementation

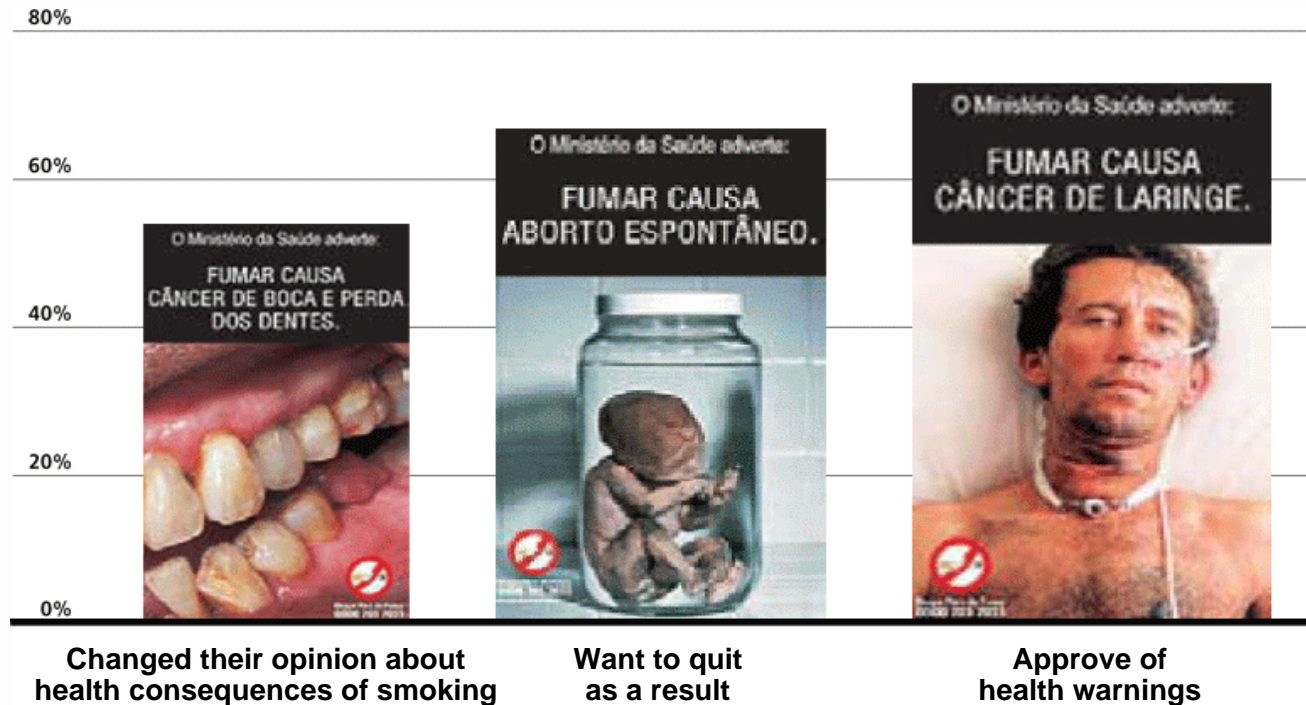


Source: WHO MPOWER Report 2008.

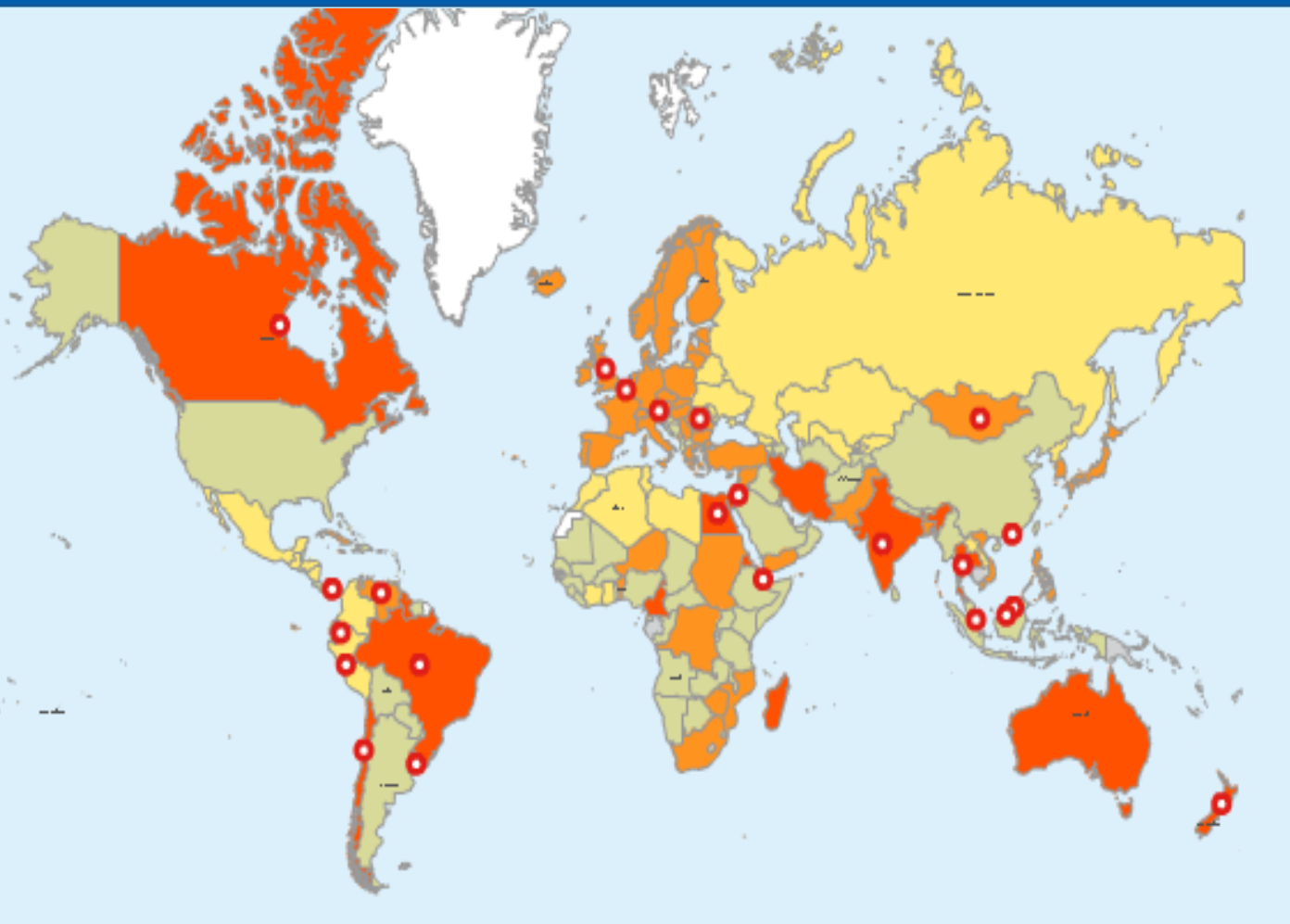




# Impact of Pictorial Warnings on Brazilian Smokers



# Health Warning Labels



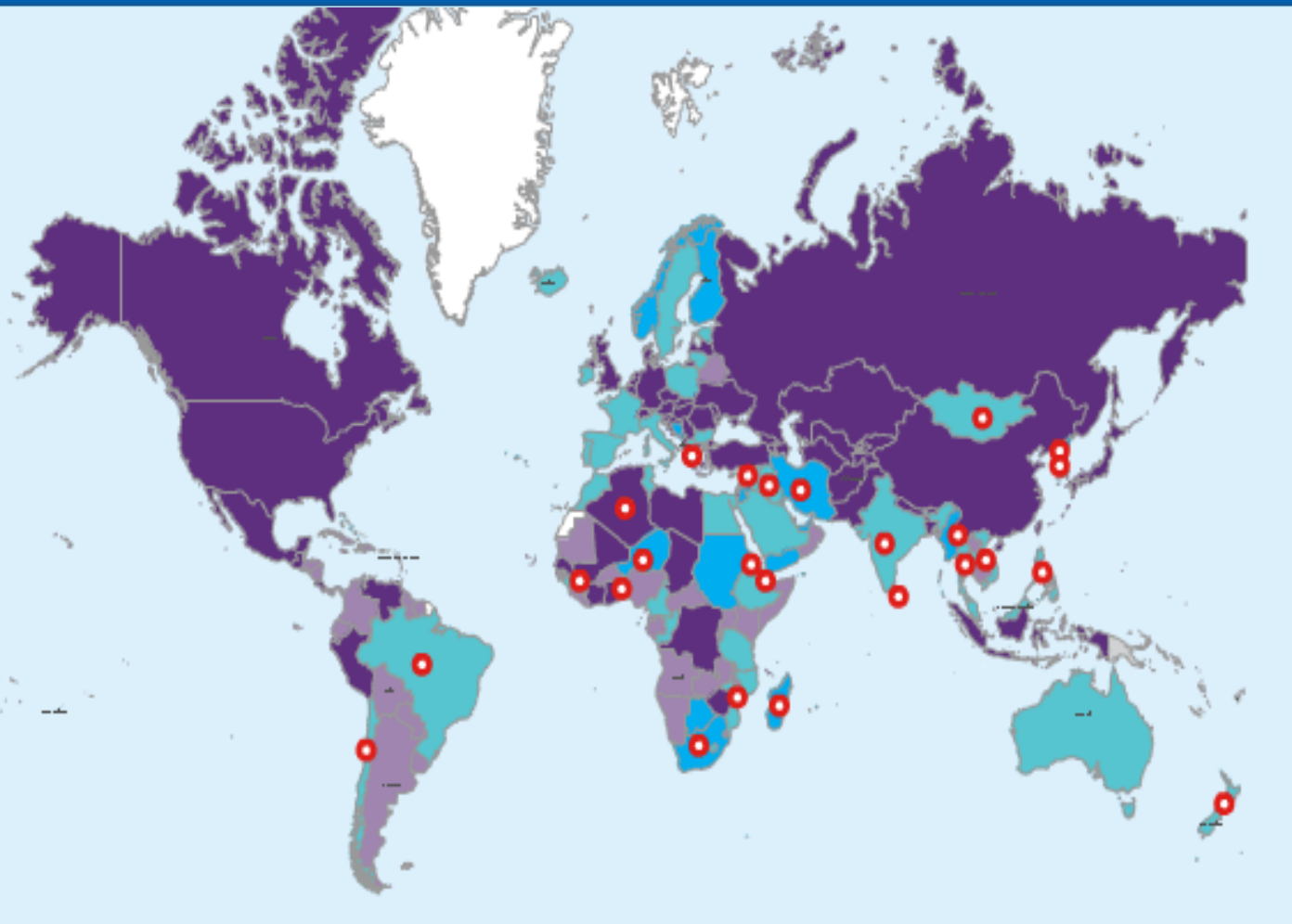
Size of Health Warnings on Cigarettes\* 2008

- X 50% and above
- X 30 - 49%
- X Less than 30%
- X No requirement
- X No Data
- X Countries requiring pictorial health warnings

\*Percent of principal display area of cigarette package legally mandated to be covered by health warning.  
Source: The Tobacco Atlas, 3rd Edition, 2008.



# Marketing Bans



Marketing Bans\* 2007

- Complete bans
- 4, 5, or 6 bans\*\*
- 1, 2, or 3 bans\*\*\*
- No bans
- No data
- Countries with ban on Internet tobacco advertising, 2007

\* Direct and indirect advertising bans, 2007.

\*\* Four, five or six direct bans and at least one indirect ban.

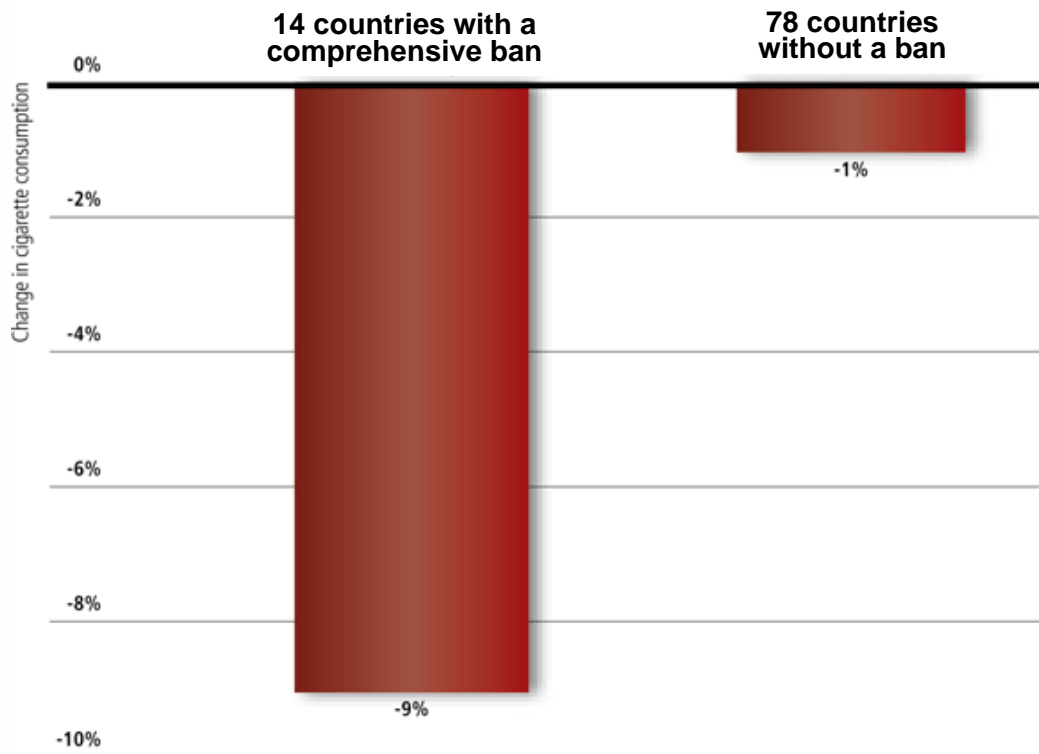
\*\*\*One, two or three direct bans or at least one indirect ban.

Source: The Tobacco Atlas, 3rd Edition, 2008.



# Comprehensive Advertising Bans Amplify Other Interventions

Average change in cigarette consumption 10 years after introduction of advertising bans in two groups of countries

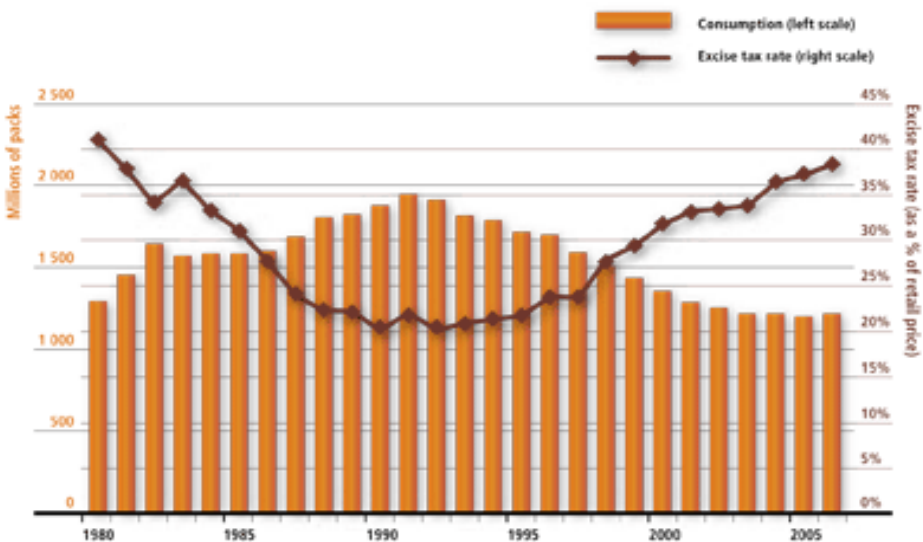


Source: Saffer H. Tobacco advertising and promotion. In: Jha P, Chaloupka FJ, eds. *Tobacco control in developing countries*. Oxford, Oxford University Press, 2000.

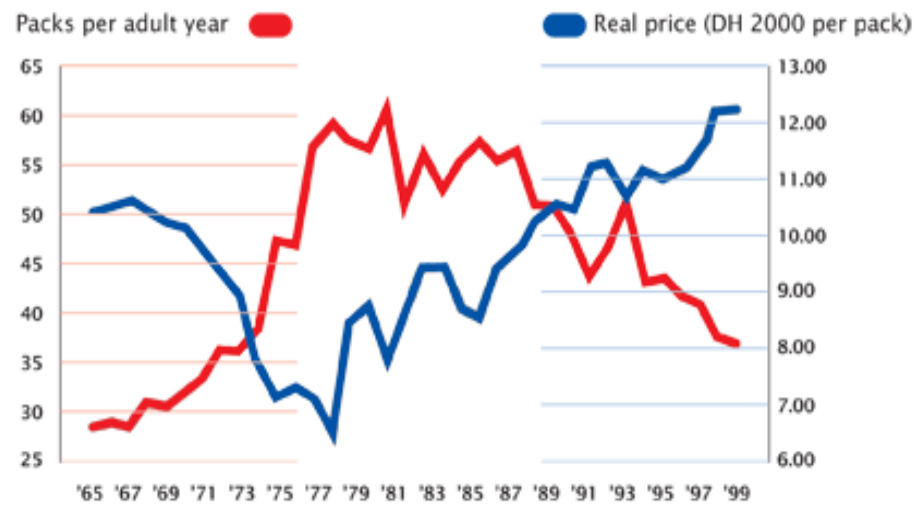


# Tobacco Prices and Consumption

Relationship between cigarette consumption and excise tax rate in South Africa



SMOKING GOES DOWN AS PRICES GO UP  
Inflation-adjusted cigarette prices and cigarette consumption in Morocco, 1965–2000

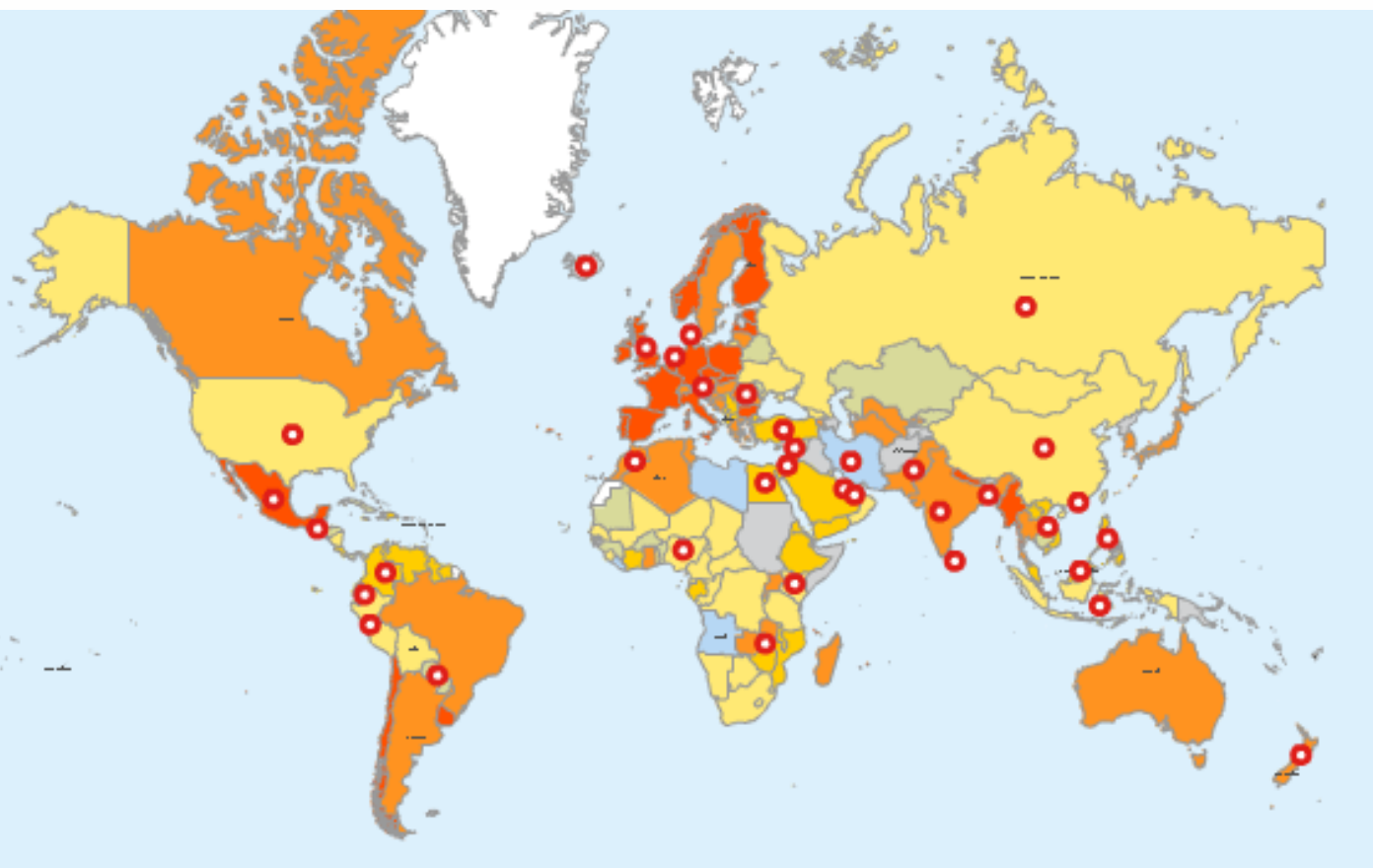


Source: Walbeek C. 2003. Tobacco excise taxation in South Africa. (left graph)

Source: Aloui O. 2003. Analysis of the economics of tobacco in Morocco. (right graph)



# Tobacco Prices and Taxes



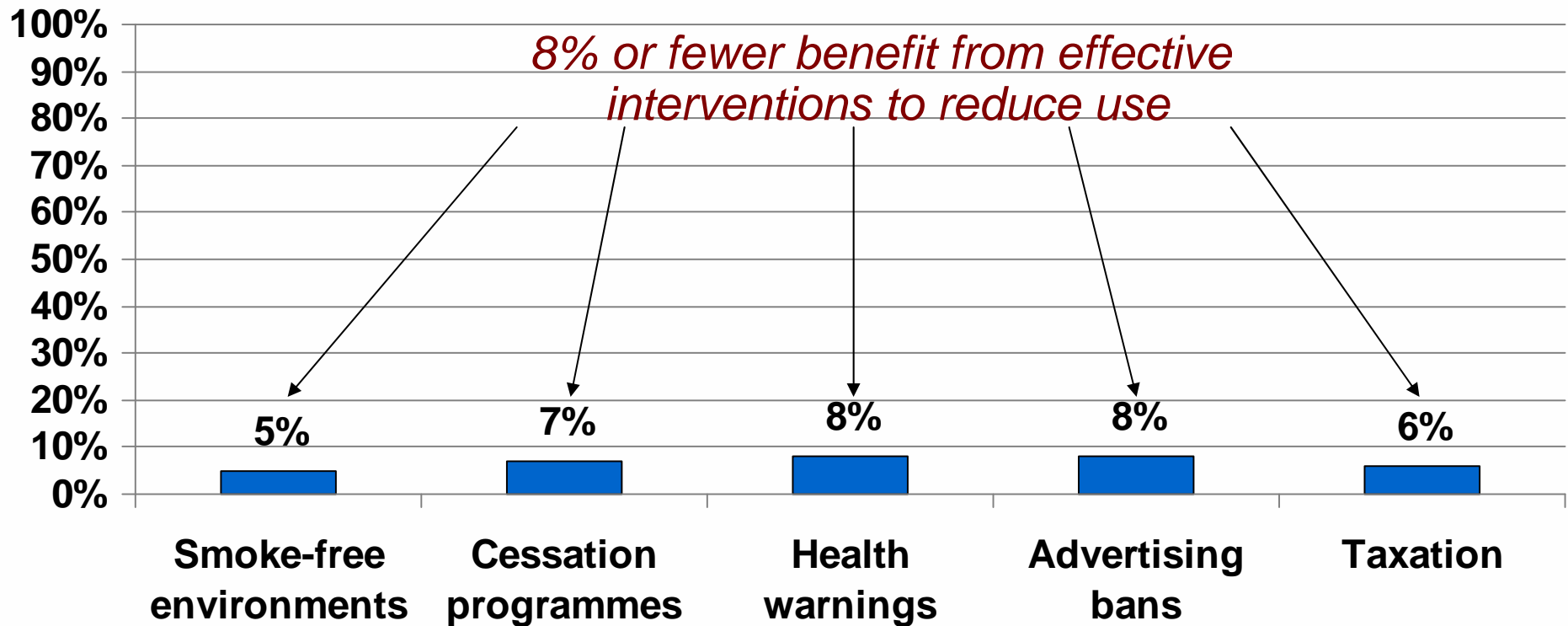
Total Tax as a proportion of Cigarette Price, 2007

- X 75% and above
- X 60%–74.9%
- X 45%–59.9%
- X 30%–44.9%
- X 15%–29.9%
- X Less than 15%
- X No Data
- X Countries where the real price of local brand cigarettes decreased between 2002 and 2007

Source: The Tobacco Atlas, 3rd Edition, 2008.

# No More Than 8% of the World's People Are Covered by Even One Effective Tobacco Control Policy

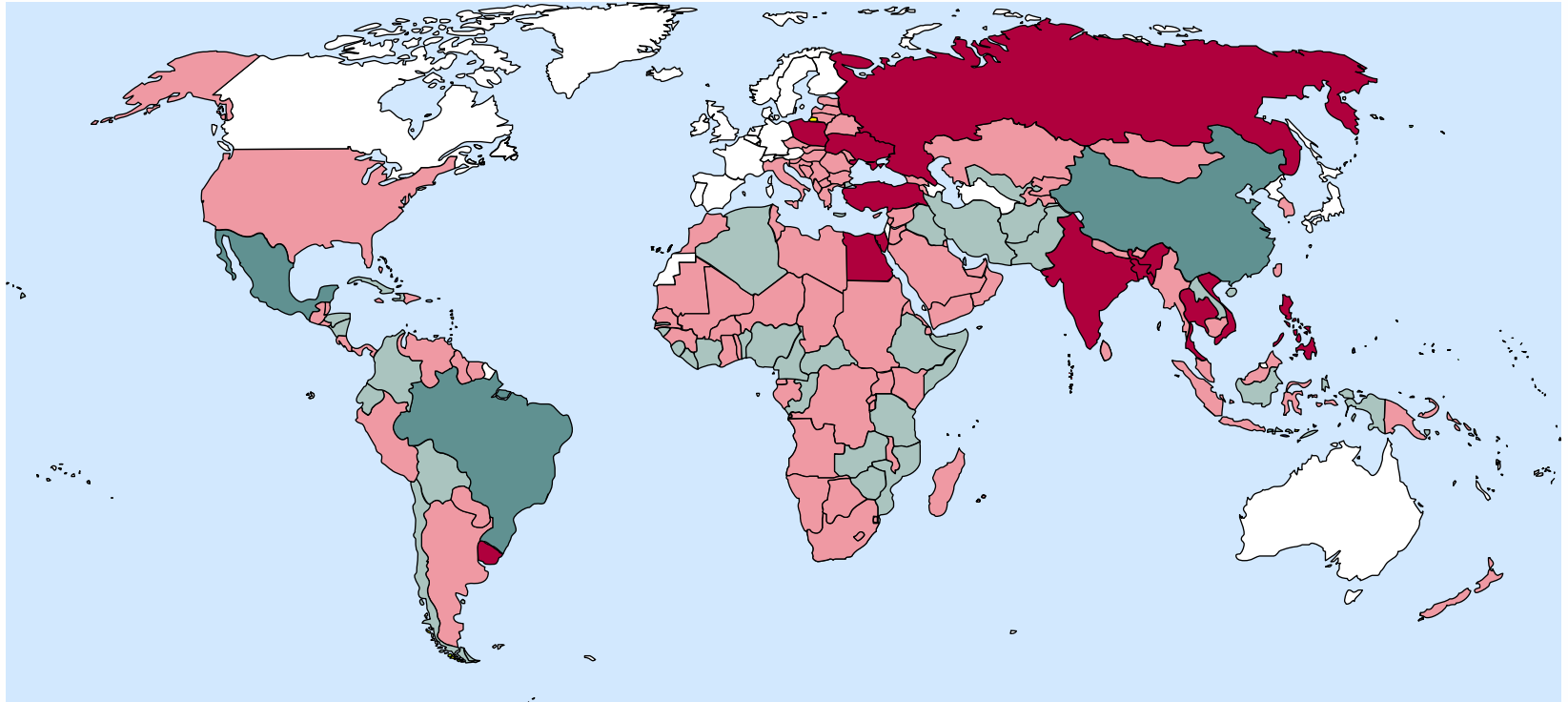
Share of world population



Source: WHO MPOWER Report 2008.



# Global Tobacco Surveillance System, 1999-2009



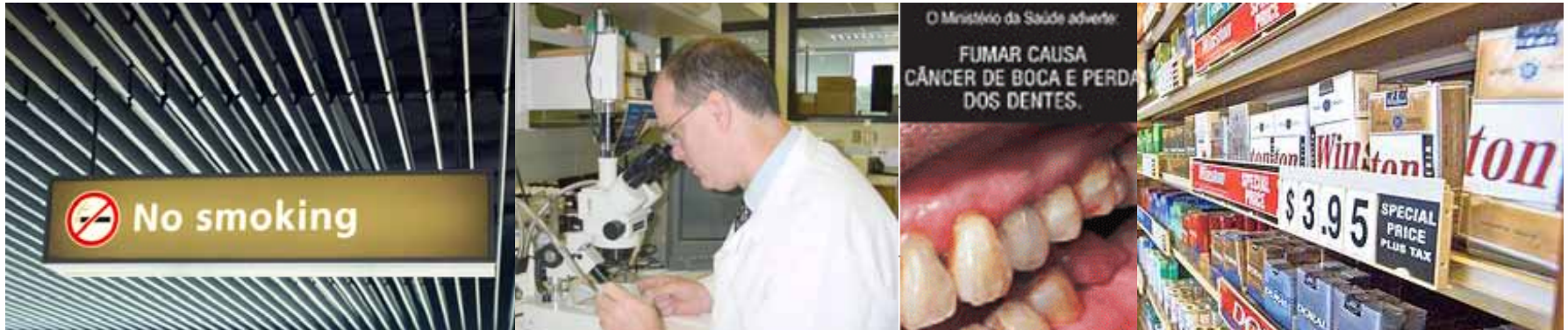
- GYTS Completed Regionally
- GYTS Completed Regionally + GATS
- GYTS Completed Nationally
- GYTS Completed Nationally + GATS

GYTS in 163 countries  
GATS in 14 countries

GYTS = Global Youth Tobacco Survey  
GATS = Global Adult Tobacco Survey



# PRODUCT REGULATION – DOES IT FIT INTO TOBACCO CONTROL?



**CAPT David L. Ashley, Ph.D.**  
***Chief, Emergency Response and Air Toxicants Branch***  
**Division of Laboratory Sciences**  
**National Center for Environmental Health, NCEH**



# Product Regulation

- ❑ **Why are differences in the design, packaging and marketing of the product important?**
- ❑ **How can product regulation reduce morbidity and mortality from tobacco use?**
- ❑ **How do we make sure that changes to the product benefit public health?**

# Some Tobacco Products Are Designed to Appeal to Youth

- ❑ Flavoring
- ❑ Nicotine control
- ❑ Marketing of sophistication
- ❑ Image of smoking



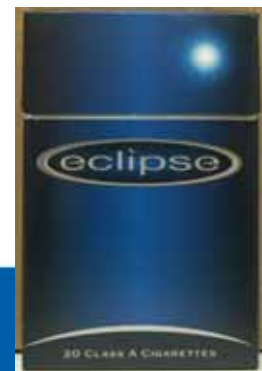
# Targeted Engineering of Tobacco Products

- ❑ Modifying the product (ventilation) to appear to lower delivery
- ❑ Developing complex sensory properties that encourage continued use
- ❑ Developing nicotine in a form that is more addictive
- ❑ Providing false promises to health conscious smokers
- ❑ Producing products that can be used when smokers cannot smoke to provide ways to keep smoking

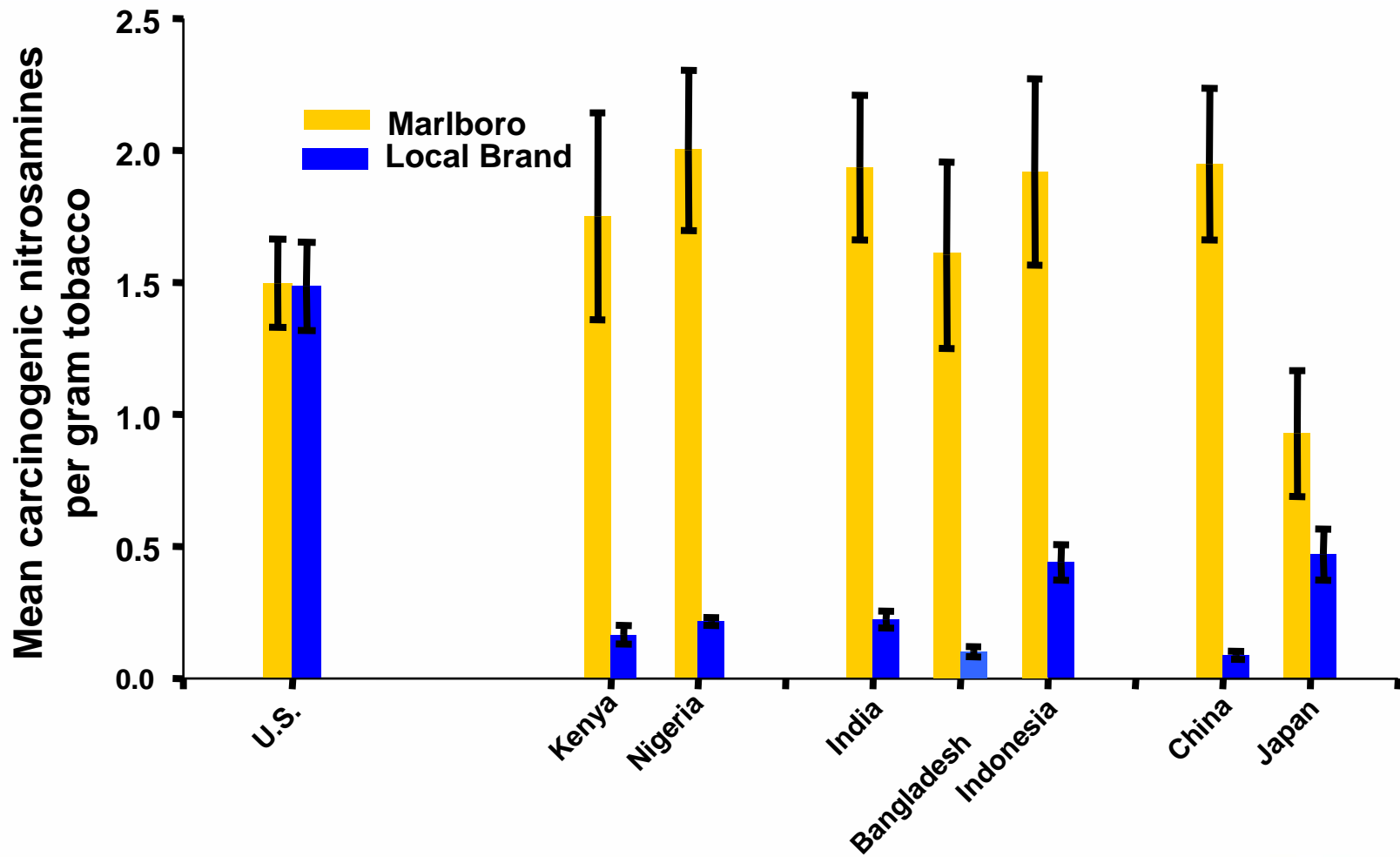


# Tobacco Product Complexity

- ❑ Many different forms of tobacco products
- ❑ Approximately 1,500 cigarette brand variants
- ❑ More than 4,000 chemicals in tobacco smoke



# Design of Tobacco Products Determines Levels of Toxic Compounds



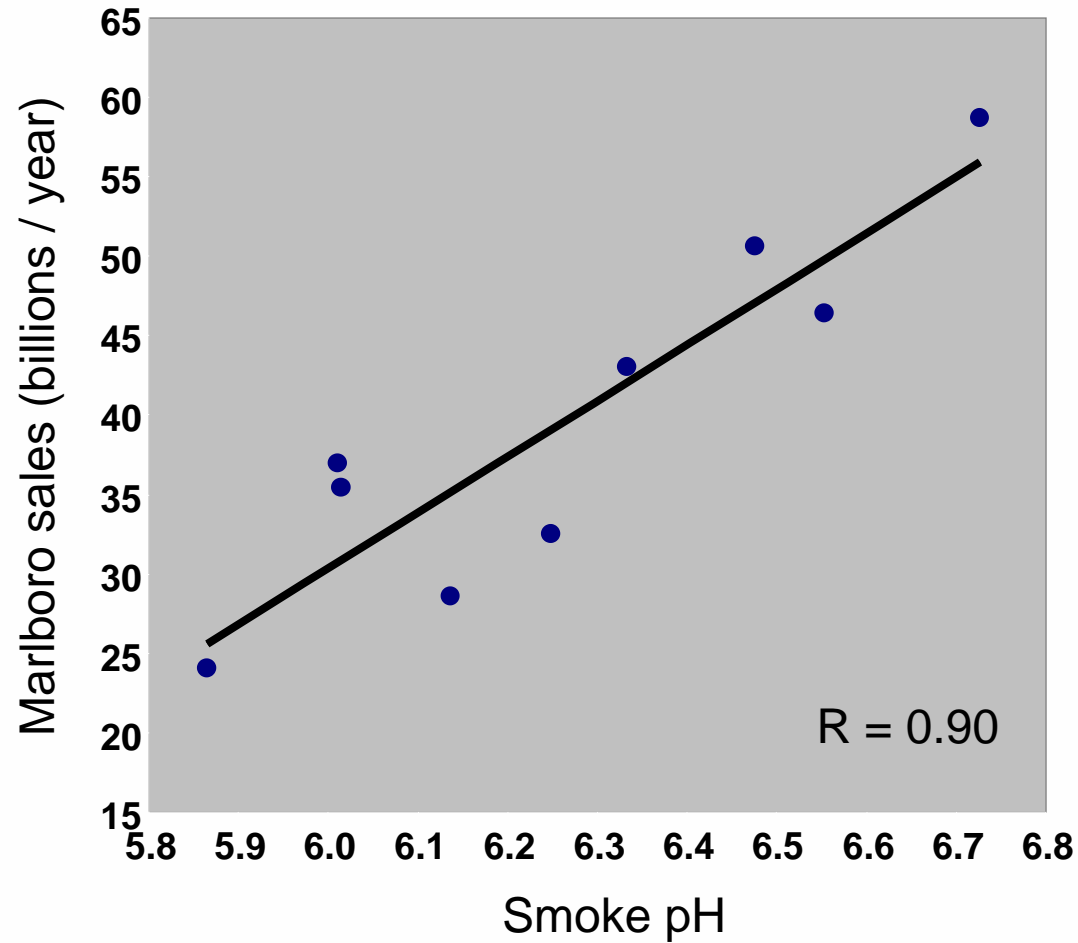
Nitrosamines in cigarette tobacco vary  
by more than factor of 20





# Design of Tobacco Products Determines Levels of Addictive Compounds

## Marlboro Sales and Smoke pH: 1964 through 1972



Source: Woods, J. and Sheets, S., RJR. Supplement A for Key Issue #3. Bates 511367302-7326)





# How Can Product Regulation Reduce Morbidity and Mortality from Tobacco Use?

- Use product standards to make the products less appealing to youth**
- Prevent changes to the products that make them more addictive or toxic**
- Use product standards to reduce exposure to toxic and addictive emissions of people who continue to use the products**

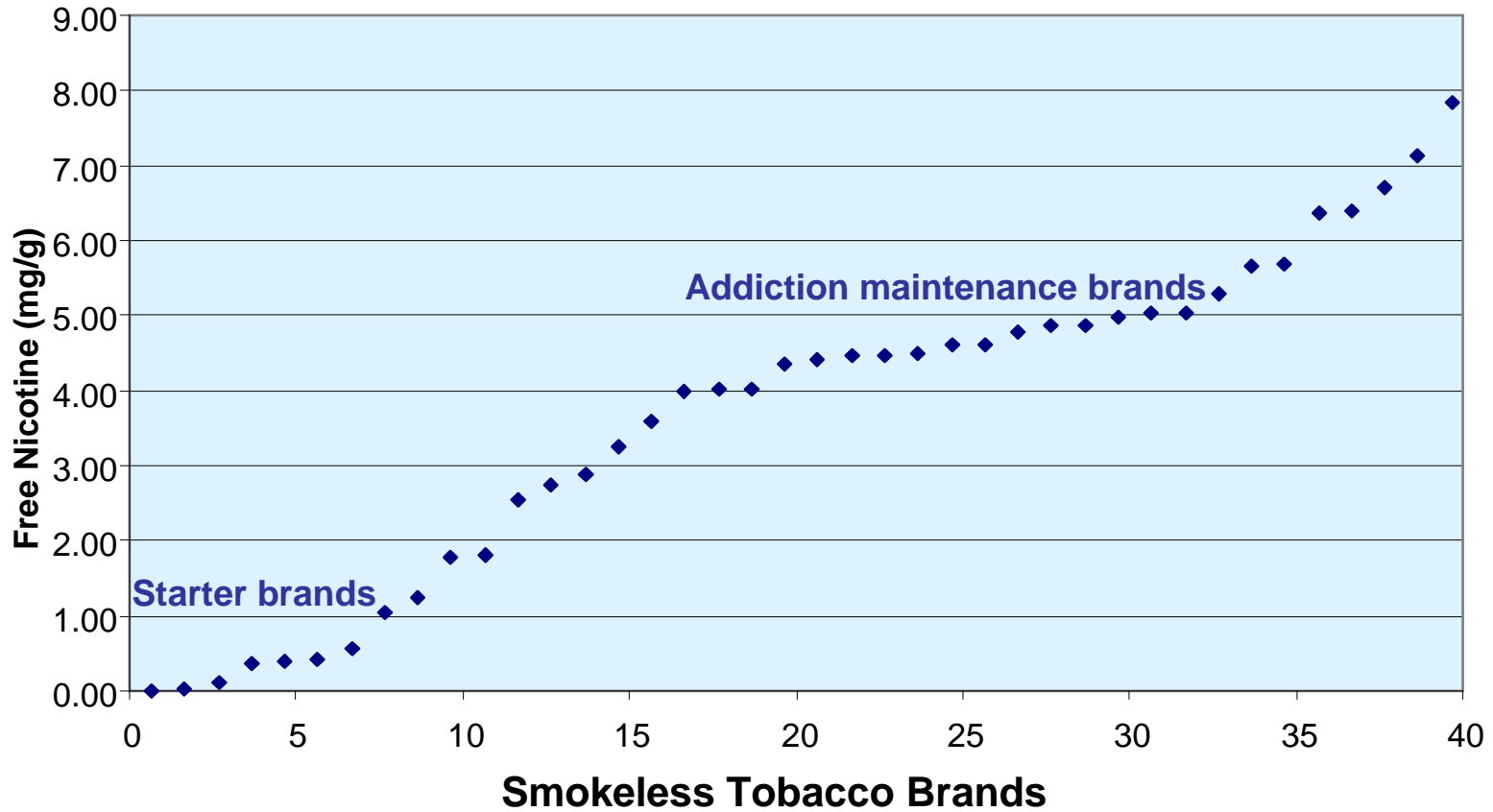




# Remove Low Free-Nicotine Smokeless Tobacco Starter Brands

## Help Block This Pathway to Addiction

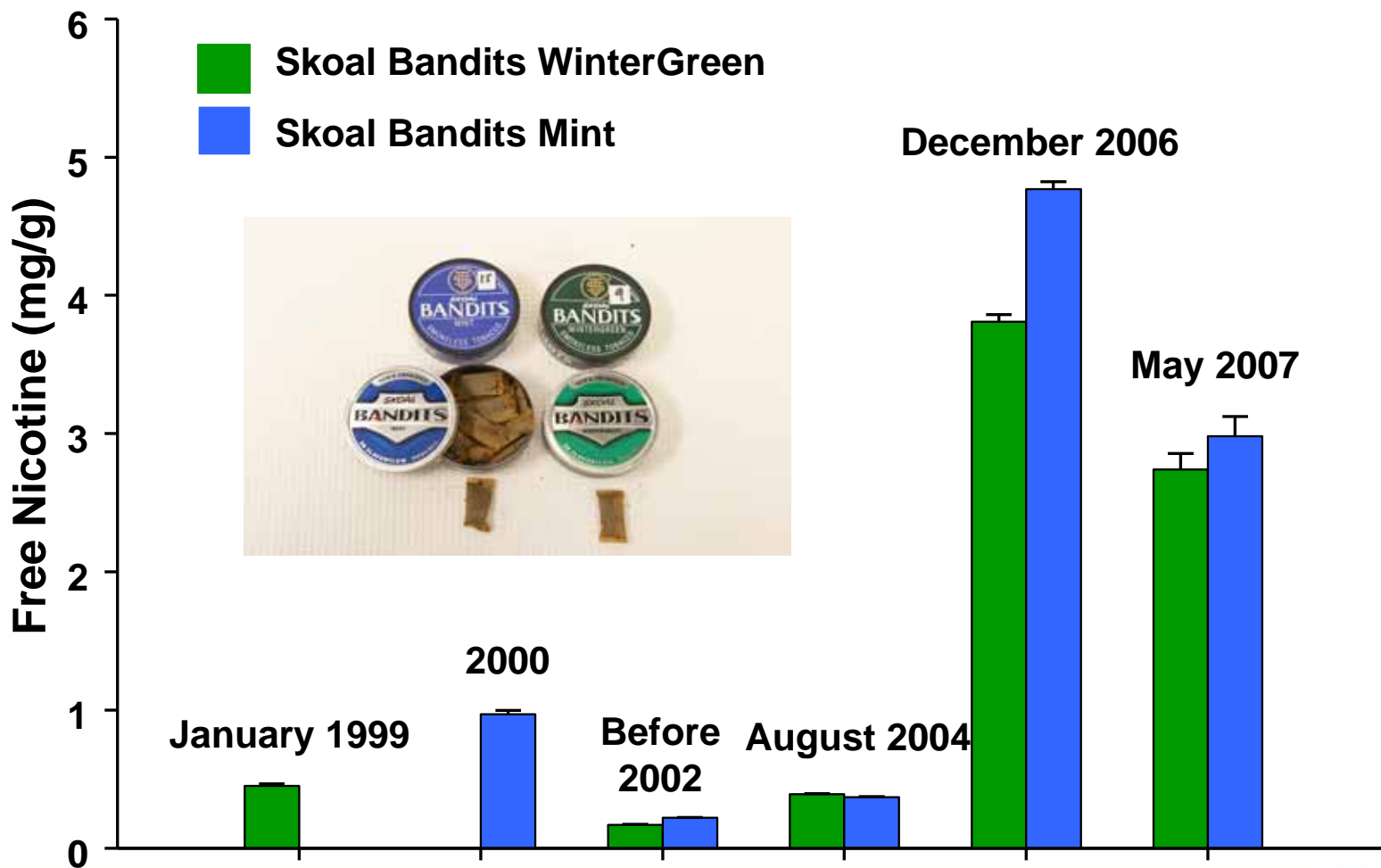
Youth start with low free nicotine products, then graduate to higher levels



Source: Richter P, Speirto FW. Surveillance of smokeless tobacco nicotine, pH, moisture, and unprotonated nicotine content. *Nicotine and Tobacco Res* 5(6):885-889, 2003.

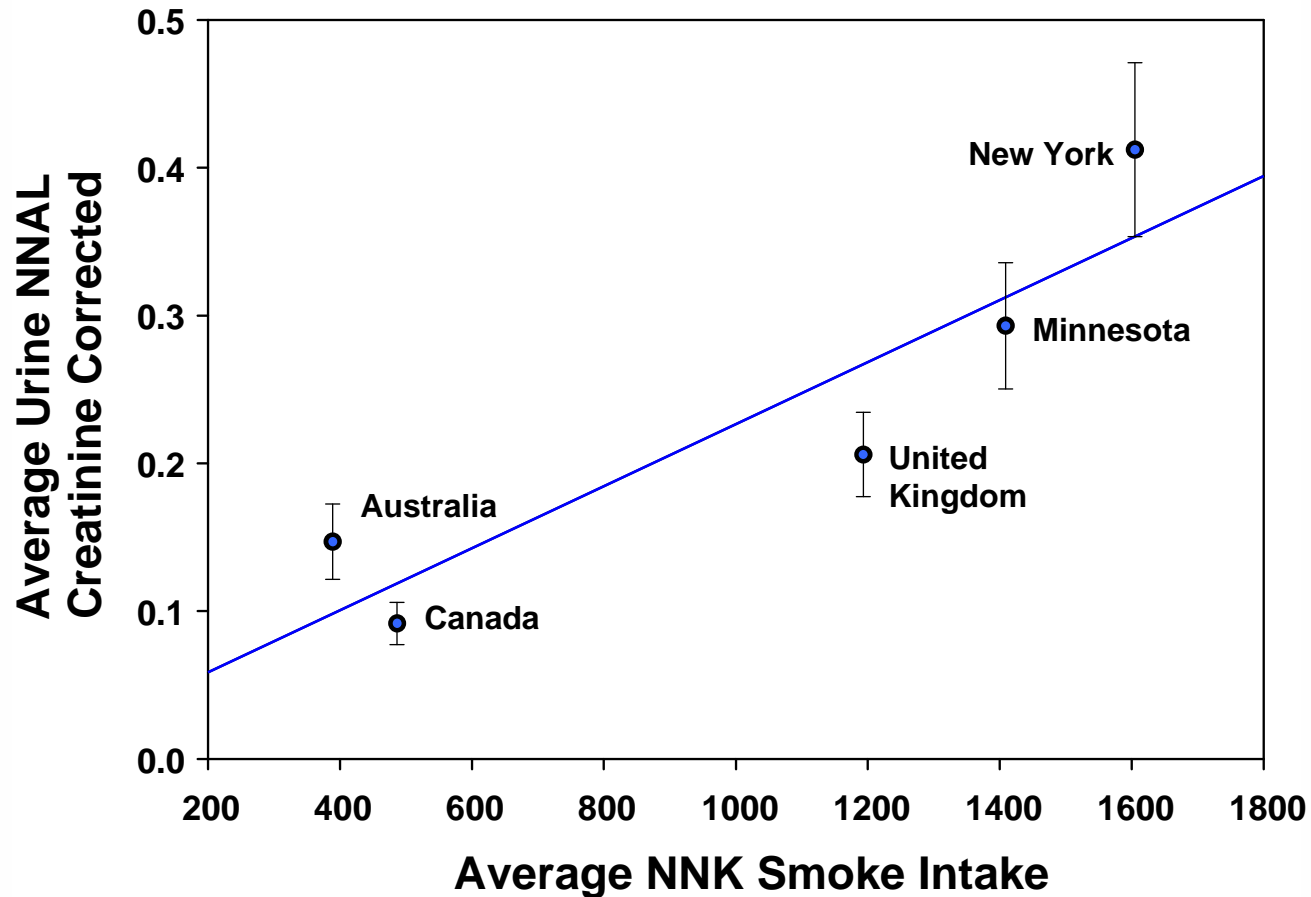


# Prevent Changes in Critical Properties without Assessing the Public Health Impact



# Set Effective Product Standards

## to Reduce Exposure to Carcinogenic Nitrosamines: Higher Lung Cancer Rates Are Associated with Higher Levels of NNAL



Source: Ashley DL, et al. Impact of differing levels of tobacco-specific nitrosamines in cigarette smoke on the levels of biomarkers in smokers, in CDC clearance.





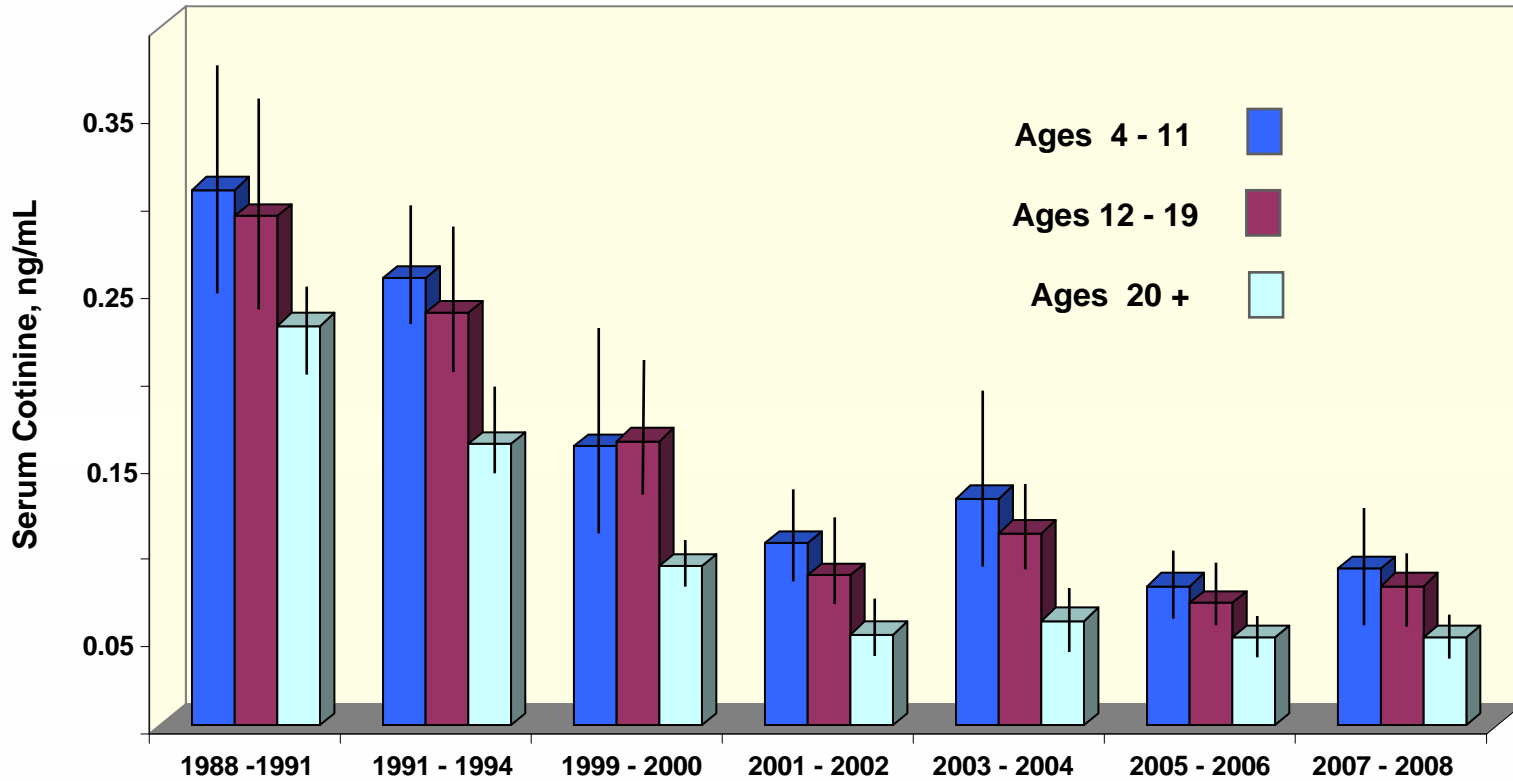
# How do We Make Sure that Changes to the Product Benefit Public Health?

- Monitor the impact of product regulation**
- Develop clear messages and communicate about product risk**
- Prevent use of product messages to imply safety without scientific validation**





# NHANES Serum Cotinine Trend in Nonsmokers by Age Group Geometric Mean (95% CI)



Totals: Age 4-11 = 9,797    Age 12-19 = 10,617    Age 20+ = 27,936



# Product Regulation: Next Steps

- ❑ Expand surveillance to collect baseline data on smokers
- ❑ Monitor for changes to the product which may be altered to circumvent product regulations
- ❑ Develop clear messages regarding the meaning of meeting these standards, particularly that it does not mean the product is now safe
- ❑ Develop ways to prevent product standards from being used to promote tobacco use

# OVERVIEW OF THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT



**Lawrence Deyton, MD, MSPH**  
***Director***  
***The Center for Tobacco Products***  
**Food and Drug Administration**



**President Barack Obama, June 22, 2009, signing the Family Smoking Prevention and Tobacco Control Act.**

**“This legislation is a victory for bipartisanship, and it was passed overwhelmingly in both Houses of Congress. It's a victory for health care reform, as it will reduce some of the billions we spend on tobacco-related health care costs in this country. It's a law that will reduce the number of American children who pick up a cigarette and become adult smokers. And most importantly, it is a law that will save American lives and make Americans healthier.”**





# Public Health and FSPTCA

- ❑ **Passage of the FSPTCA is a significant new component of the larger goal of tobacco control**
- ❑ **Still a lot of work ahead of all of us**
- ❑ **Presents opportunities for all of us in public health to increase action on tobacco control at every level.**
- ❑ **FSPTCA established a new standard for FDA: to regulate tobacco products based on a public health and population health standard**

# FDA Tobacco Control Goals

- Prevent youth tobacco use**
- Help adults who use tobacco to quit**
- Promote public understanding of contents and consequences of use of tobacco products**
- Develop science base and begin meaningful product regulation to reduce the toll of tobacco-related disease, disability, and death**



# Authority Granted Under FSPTCA

## SEC. 102. FINAL RULE.

- ❑ Requires Secretary to issue a final rule (on first Federal Register publication date six months after enactment) regarding advertising of, and access to, tobacco products.
- ❑ Requires that the rule become effective one year after enactment.
- ❑ Requires the final rule to be identical to the advertising and access regulations promulgated by FDA in 1996, except as specifically provided.
- ❑ Authorizes the Secretary to modify the final rule, but provides that such modification shall be through the normal rule making process.



# Authority Granted Under FSPTCA

## **SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.**

- ❑ Requires manufacturers or importers to submit information to the Secretary, under various timeframes, on—**
  - tobacco product ingredients;**
  - nicotine content;**
  - research on the health and physiological effects of tobacco product use; and**
  - marketing practices and effectiveness.**



# Authority Granted Under FSPTCA

## SEC. 905. ANNUAL REGISTRATION.

- ❑ **Requires annual registration, with the Secretary, of each establishment in the U.S. engaged in the manufacture, preparation, compounding, or processing of tobacco products. FDA must inspect registered establishments at least every two years.**
- ❑ **"Substantial equivalence." Any registered establishment planning to introduce a new tobacco product (not commercially marketed in the U.S. as of February 15, 2007) must report to the Secretary how the product is "substantially equivalent" to a tobacco product marketed as of such date, or to a product marketed after such date which meets applicable requirements.**
- ❑ **If not "substantially equivalent", product must undergo premarket review as a new tobacco product, under section 910.**



# Authority Granted Under FSPTCA

## SEC. 907. TOBACCO PRODUCT STANDARDS.

- ❑ Artificial and natural flavors banned. **Prohibits, three months after enactment, any cigarette from containing characterizing fruit flavors, herbs or spices (including clove). Menthol is expressly excepted from the prohibition, but still subject to Secretarial action.**
- ❑ Secretary can restrict flavors not specifically identified. **The Secretary may take action under this or other sections against menthol or any other flavoring, herb, or spice not included in the prohibited list.**
- ❑ Other standards possible. **The Secretary can adopt other tobacco product standards as the Secretary determines appropriate for protecting public health, including for nicotine yields and reduction or elimination of other constituents.**
- ❑ Menthol cigarettes and dissolvable tobacco products. **The Secretary must refer the issues of menthol in cigarettes and dissolvable tobacco products to the Tobacco Products Scientific Advisory Committee for report and recommendations within one year (with respect to menthol) and within two years (with respect to dissolvable tobacco products).**

# Authority Granted Under FSPTCA

## SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TOBACCO PRODUCTS.

- Premarket review required **for new tobacco products (i.e., not commercially marketed as of February 15, 2007, or modified after that date);**
- Substantial equivalence. **Premarket review NOT required for new tobacco products "substantially equivalent" to products on market as of February 15, 2007, or exempt from "substantial equivalence" requirements by regulation;**

# Authority Granted Under FSPTCA

## SEC. 911. MODIFIED RISK PRODUCTS.

- ❑ Described. **Modified risk products are tobacco products characterized as `light,' `mild,' or `low,' or otherwise for use to reduce harm or the risk of tobacco-related disease associated with other tobacco products.**
- ❑ Conditions for marketing. **Modified risk products can only be marketed if the Secretary, after reviewing a product application, determines that the product:**
  - **will significantly reduce harm and the risk of tobacco-related disease to individual users (compared to other tobacco products), and**
  - **benefit the health of the population as a whole, taking into account the impact on both users and nonusers of tobacco products.**
- ❑ Not "modified risk products". **“Smokeless” tobacco products are not modified risk products, nor are products approved by FDA as drugs or devices for treatment of tobacco dependence.**



# Authority Granted Under FSPTCA

## **SEC. 917. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.**

- ❑ Requires the Secretary, within 6 months after enactment, to establish the Tobacco Products Scientific Advisory Committee.**
- ❑ The Committee will submit reports or recommendations on:**
  - The impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics and other racial and ethnic minorities**
  - The nature and impact of the use of dissolvable tobacco products on the public health, including such use on children**
  - The effects of the alteration of nicotine yields from tobacco products and whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved**
  - Any application submitted by a manufacturer for a modified risk tobacco product**

# Authority Granted Under FSPTCA

## SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.

- Amends the Federal Cigarette Labeling and Advertising Act to specify nine new required warning labels, one of which must appear on cigarette packages and advertisements within 1 year of enactment.
- The warnings must comprise the top 50 % of the front and rear panels of the package and at least 20% of the related advertisements.
- Requires the Secretary to issue regulations requiring color graphics depicting the negative health effects of smoking, to accompany the written warnings.



# State and Local Involvement & Coordination

- ❑ The Secretary shall contract with the States **in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this Act.**
- ❑ State and local activities. **Requires the Secretary, within three months of enactment, to inform State, local, and tribal governments of their authorities with respect to tobacco products as provided under this Act.**
- ❑ Community Assistance. **Permits communities to seek assistance from the Secretary to prevent underage tobacco use.**

# State and Local Involvement & Coordination

- ❑ **FDA bridge to state tobacco control programs**
- ❑ **The tobacco control efforts in place in states and localities are crucial**
- ❑ **FDA will seek opportunities to support state activities related to the FSPTCA**

# Intra-HHS Coordination

- ❑ **Assistant Secretary for Health**
- ❑ **CDC: Surveillance, epidemiology, product analysis**
  - **Office on Smoking and Health**
  - **National Center for Environmental Health**
- ❑ **SAMHSA: Tobacco outreach and surveillance**
- ❑ **NIH: Tobacco Research Topics**

# Major Accomplishments To Date

## June

FSPTCA signed into law

## July

Listening session with State and local officials

## August

Established the Center for Tobacco Products

Established the Scientific Advisory Committee

Created the User Fee Program

## September

Listening sessions with public health advocates and tobacco industry

Hired and introduced Center Director

Enacted the ban on flavored cigarettes

## October/November

Issued Final Guidance on Registration and Listing (section 905)

Issued Draft Guidance on Ingredient Submission (section 904)





# Regulatory Deadlines: Next Steps

**January 2010**

**Industry ingredient submission**

**April 2010**

**Reissuance of 1996 Rule**

**July 2010**

**Ban on misleading marketing terms**

**July 2010**

**Smokeless tobacco warning labels**

**October 2012**

**Cigarette warning labels**



# Challenges and Opportunities

- ❑ **FDA regulatory authority new to this industry**
- ❑ **Creating a major new regulatory organization**
- ❑ **Meeting aggressive statutory deadlines**
- ❑ **Striving to meet diverse expectations from stakeholders**
- ❑ **Collaborating with state and local agencies on tobacco control**
- ❑ **Establishing effective and interactive channels for public communication, education and outreach with all stakeholders**



# PUBLIC HEALTH GRAND ROUNDS

Office of the Director

November 18, 2009

