

A Comparative Analysis of Policy Approaches by the U.S. and Japan to Tobacco Control



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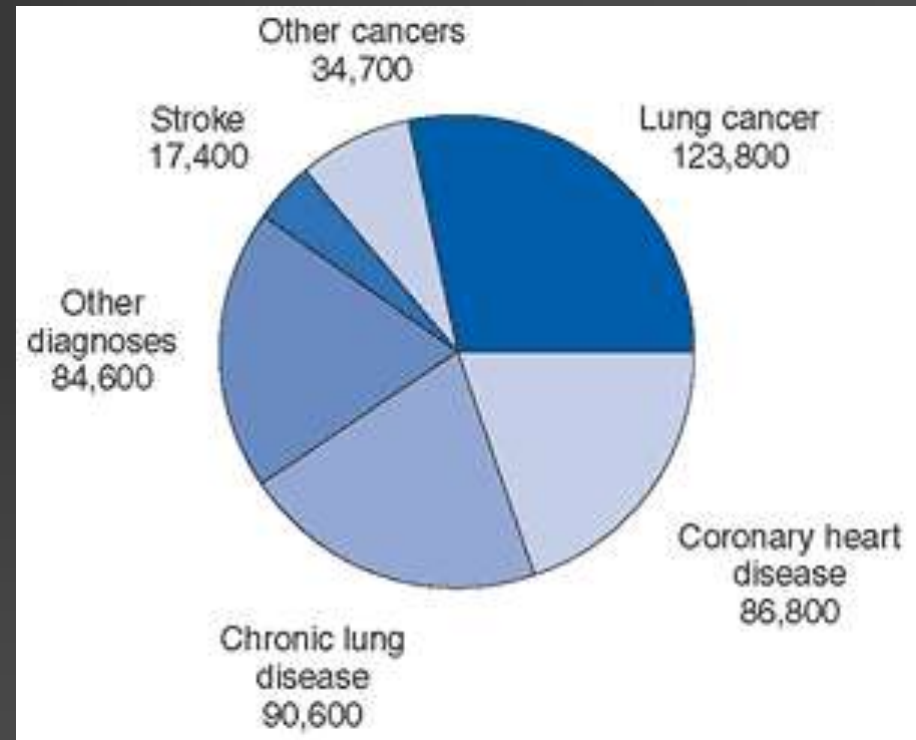
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Overview

- Reason for Tobacco Control
 - Mansfield Fellowship
 - Tobacco Control Strategies
 - Challenges for Japan and US
 - Opportunities to inform U.S. tobacco control policy
-

US Tobacco-related deaths & disease

- About 20.9% of U.S. adults (45.1 million people) are current cigarette smokers
- 430,000 U.S. deaths per year due to cigarette smoking
 - 30% of all cancer deaths
 - 87% of lung cancer deaths
- Smokers die 13 to 14 years earlier than nonsmokers
- 8.6 million people in the US have at least one serious illness caused by smoking



The Public Health Case For Comprehensive Tobacco Control in Japan

- 112,000 tobacco-related deaths in Japan in 2000
- Health Ministry estimated health care costs from smoking at 4 trillion yen in 1997
- Lung cancer has been leading cause of cancer death among Japanese men since 1993
 - 3-fold increase in lung cancer deaths among men since 1965
 - In Japan, a smoker has a 6 times greater chance of contracting lung cancer than a nonsmoker
- 47% smoking prevalence among Japanese men (down from 82% in 1965) and a rising 14.5% rate among women (2006 “Tobacco Atlas”)
- Japan has the 4th highest per capita cigarette consumption rate in the world (2,920 cigs/year)
- The cost of a pack of cigarettes in Japan is amongst the lowest in developed countries
- *Interest in quitting is rising, but too few quit attempts succeed*

Leading Causes of Death

主な死因

■ Japan - 2005

- Cancer がん (300,000)
- Heart diseases 心臓病
- Stroke 脳卒中
- Pneumonia 肺炎
- Accidents 不慮の事故

■ US - 2003

- Heart diseases 心臓病
- Cancer がん (550,000)
- Stroke 脳卒中
- Emphysema, chronic bronchitis 肺炎
- Accidents 不慮の事故

Mike and Maureen Mansfield Fellowship



- U.S. federal government employees opportunities:
 - Develop in-depth understanding of Japan
 - Learn how Japan's government works
 - Establish relationships: GOJ and others
- Training
 - 1 yr language training and area studies (U.S. & Japan)
 - 1 yr in GOJ offices

Objectives

- Exchange information about health promotion and cancer prevention and control strategies
 - Learn about decision making process for:
 - Setting life-style related health priorities
 - Conducting surveillance of risk factors for life-style related disease (cancer, stroke, heart disease, etc)
 - Strengthen joint U.S.-Japan collaboration on health promotion and cancer-related topics
-

Placement Plan



MHLW --- NIPH

Shizuoka

NCC

Sep Oct Nov Dec Jan Feb Mar Apr May Jun July Aug

MHLW: Ministry of Health, Labour and Welfare 厚生労働省

- Office for Life-Style Related Diseases Control, Health Service Bureau

Shizuoka Prefectural Government 静岡県

- Department of Health & Welfare (Office of Disease Control & Prevention)

NCC: National Cancer Center 国立がんセンター

- Research Center for Cancer Prevention and Screening (RCCPS)

Ministry of Health Labor & Welfare



- Office for Life-Style Related Diseases Control (9/2006-5/2007)
- Learned about national health promotion plans to reduce lifestyle related diseases
- Synthesized data for policy-makers
- Provided consultation & information to respond to public health related statements and inquiries from other ministries, politicians, the media, and private industry

Shizuoka Prefectural Government

- Department of Health & Welfare, Office of Disease Control & Prevention (2/2007-3/2007)
- Exchanged scientific information with physicians, policy-makers & researchers leading public health activities in Japan
- Visited hospitals, medical examination centers, local government offices
 - Regional Health Plans
 - Tobacco control policies
 - Cancer screening services
 - Collection of health information



National Cancer Center

- Center for Cancer Control and Information Services (6/2007-8/2007)
- Learn more about cancer control in Japan
 - Estimate cancer incidence and mortality
 - Cancer prevention and screening
 - Cancer registry
 - Future cancer control goals





Addressing the Tobacco Epidemic in Japan and the United States

Top National Health Issues

Japan---Health Japan 21

Specific Areas

- Nutrition and Diet
- Physical Activity & Exercise
- Tobacco
- Alcohol
- Rest / Promote mental health
- Dental health
- Diabetes
- Cardiovascular Diseases
- Cancer

US---Healthy People 2010

Leading Health Indicators

- Overweight and Obesity
 - Physical Activity
 - Tobacco Use
 - Substance Abuse
 - Mental Health
 - Responsible Sexual Behavior
 - Injury and Violence
 - Environmental Quality
 - Immunization
 - Access to Health Care
-

Strategies for Tobacco Control

Japan Health Japan 21 Goals

- Prevent underage smoking
- Environmental building for elimination (zoning) and reduction of passive smoking
- Support of persons try to give up smoking
- Disseminate knowledge

SLOGAN: “reduce smoking prevalence in half by 2010”

US Comprehensive Tobacco Control Strategies (CDC)

- Restrict access to minors
 - Reduce exposure to second hand smoke
 - Treating nicotine addiction
 - Limit impact of tobacco advertising
 - Increase price of tobacco products
-



Similar Objectives:
Prevent youth smoking



Health Japan 21 Tobacco Goal

4.2 Eliminate underage smoking

- Junior high school 1st year
 - Boys: 7.5%, girls 3.8%
- High school 3rd year
 - Boys: 36.9%, girls 15.6%

Goal=0% in 2010



Numerical target for Japan smoking rate

- Current smoking rate in Japan
 - Men 43.3%
 - Women 12%

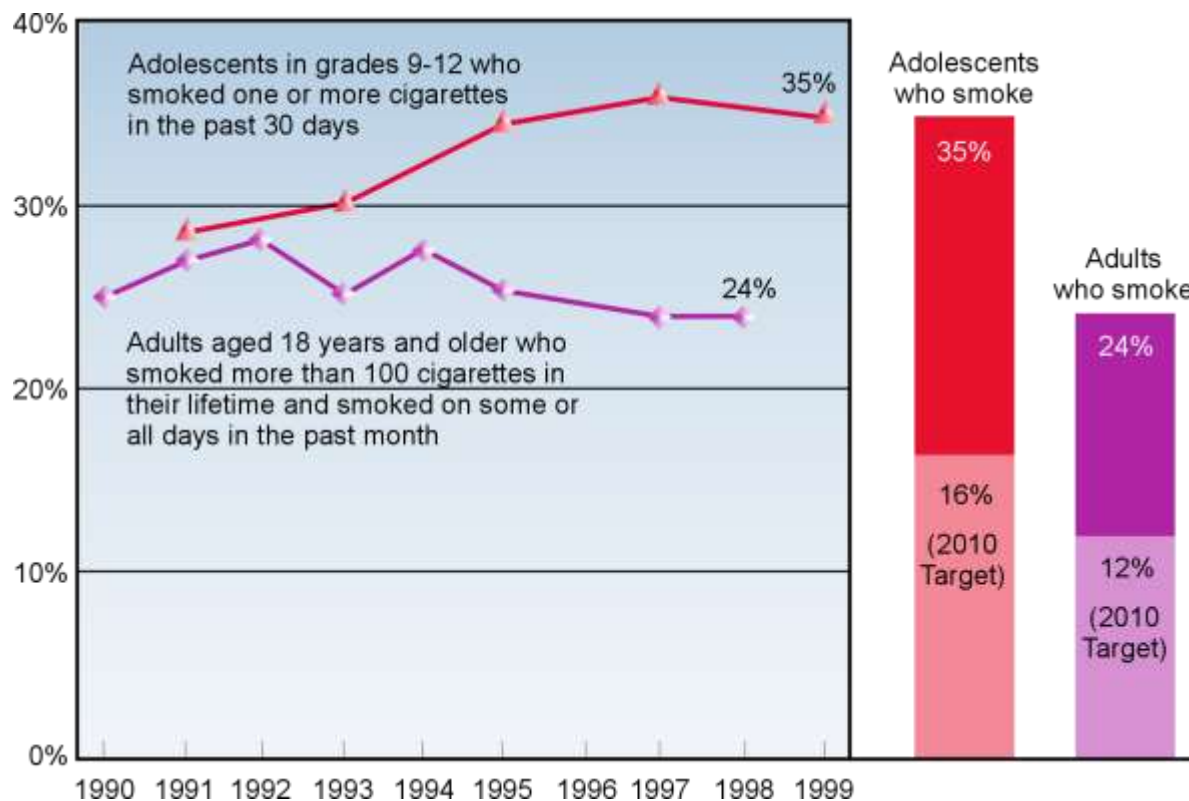
“The ministry had considered stating a 50% reduction as a numerical target. But this figure was abandoned after a series of protests was lodged by Japan Tobacco Inc., tobacco growers and some Liberal Democratic Party members who said it was an inappropriate intervention by the government in personal preference.”

Source: Yomiuri Shimbun (October 17, 2006)

Tobacco Use

Healthy People 2010 Leading Health Indicator

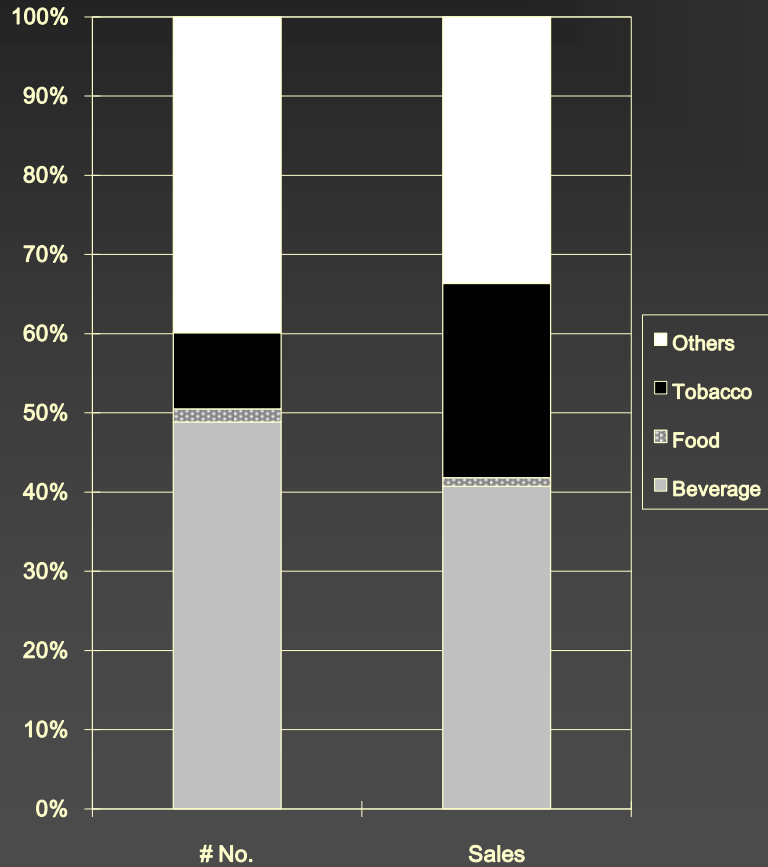
Cigarette smoking, United States, 1990–99



Vending machines in Japan & US



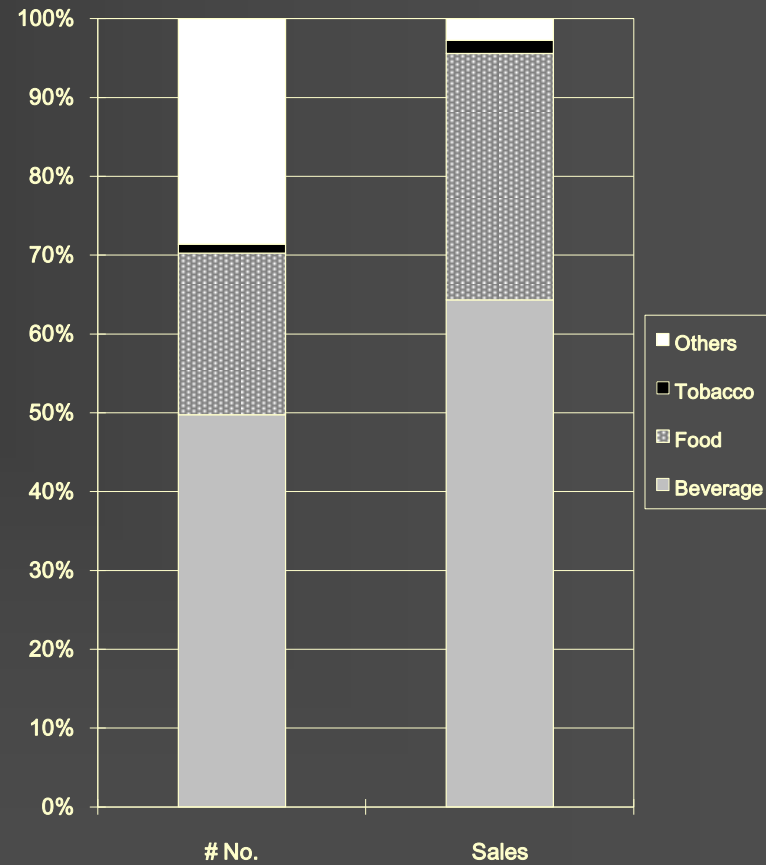
Japan (2007)



5.40 mil.# 6.9 tril. YEN

Data: JVMMA (2008)

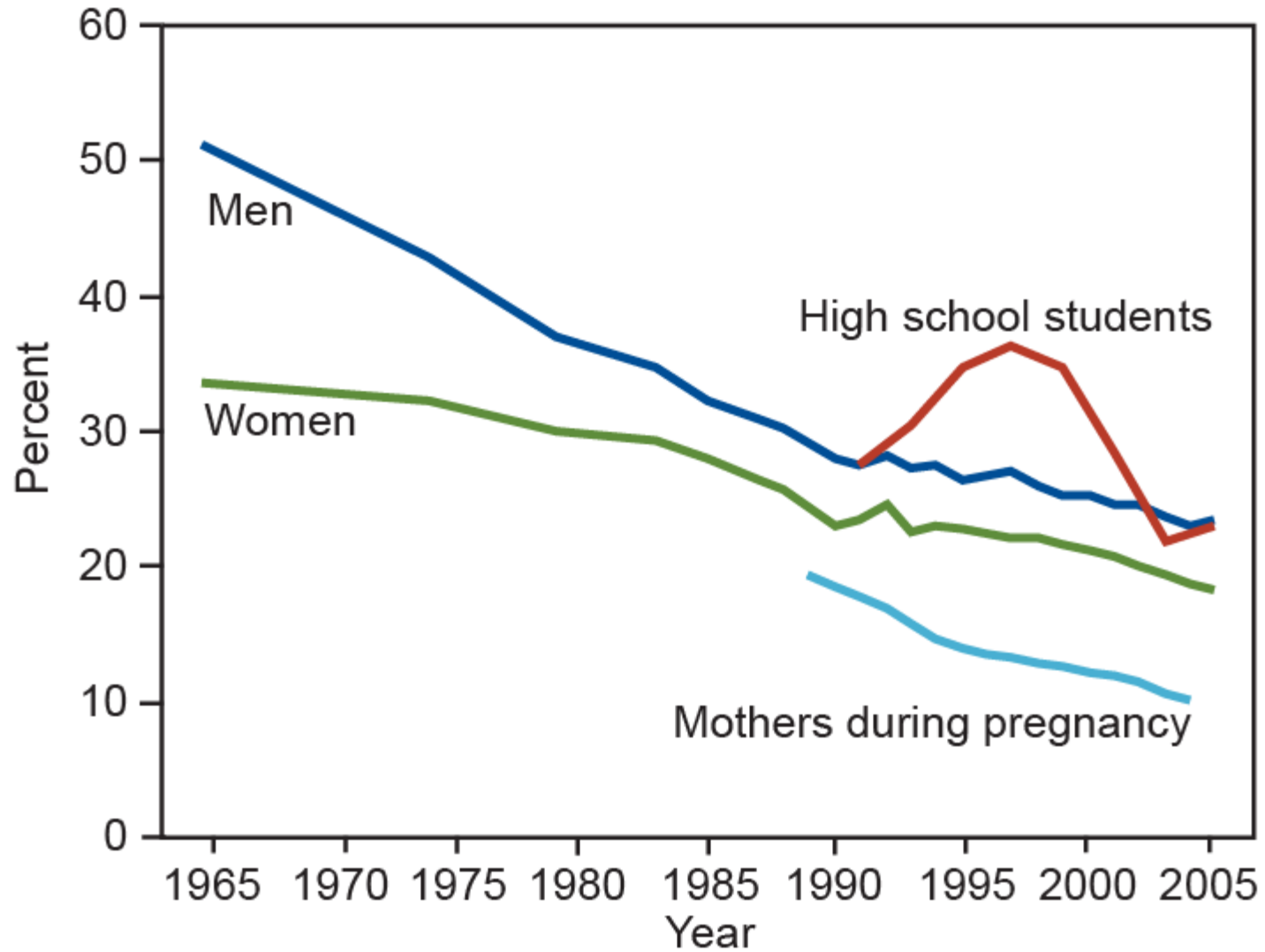
US (2006)



7.83 mil.# 46.8 bil. USD

approx. 62.7 bil. USD (1\$=110JPY)

Cigarette smoking



SOURCES: Centers for Disease Control and Prevention, National Center for Health Statistics, *Health, United States, 2007*, Figure 9. Data from the National Health Interview Survey, Youth Risk Behavior Survey, National Vital Statistics System.

Advertising to Youth?



- Enforce laws prohibiting illegal tobacco sales to minors
- Retailer license suspension for sales to minors
- Eliminate tobacco advertising and promotion targeting adolescents and young adults

The Sunny Side of

truth



- **truth** (February 2000) is the largest youth smoking prevention campaign in the U.S.
 - Exposes tactics of the tobacco industry
 - Truth about addiction
 - Health effects & social consequences of smoking
- 80% of smokers begin using tobacco before the age of 18; the primary focus is youth aged 12 to 17 years.
- Focus is on changing social norms to reduce youth smoking
 - March 2002 --- 300,000 fewer youth smokers (AJPB March 2005)
- BecomeAnEx.org (2008)



Similar Objectives: Environmental Tobacco Smoke

Second Hand Smoke (SHS)

たばこの煙の成分

- 4,000 chemicals in tobacco smoke
4000の化学物質が含まれる
- 43 cause cancer in humans & animals
43の人間と動物のがんの原因となる
- 3,000 nonsmokers dies of lung cancer (in US)
アメリカでは毎年3000人の非喫煙者が肺がんで死亡
- 150,000-300,000 infants and children (under 18 months) experience lower respiratory tract infections (in US)
15万～30万人の乳幼児や子供(18歳以下)が気管支炎等に罹患

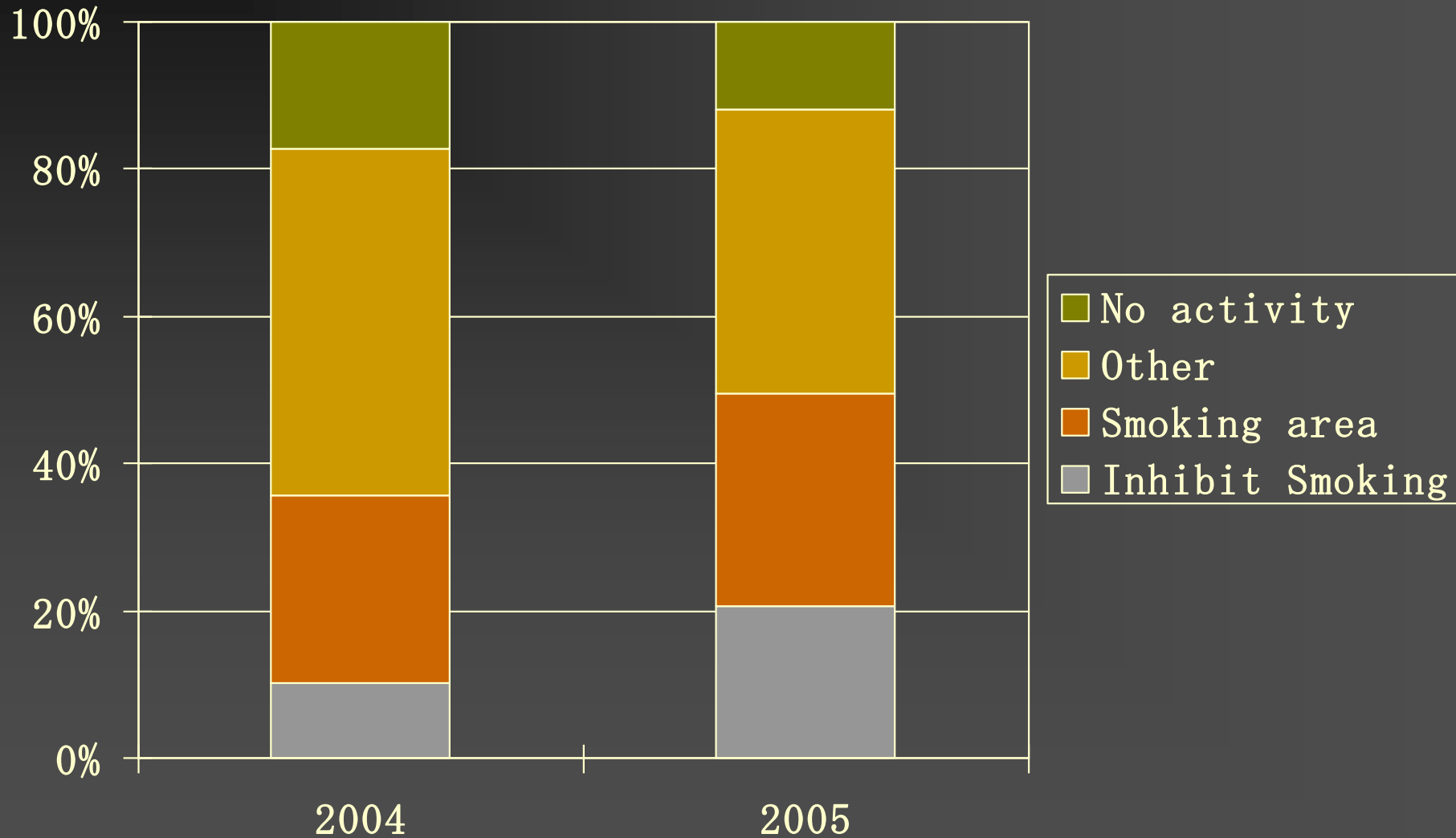
Health Japan 21

Objective for Controlling SHS Exposure

- Widespread zoning of smoking areas in public places and workplaces, and dissemination of knowledge on effective zoning of smoking areas. (2010 target 100%)



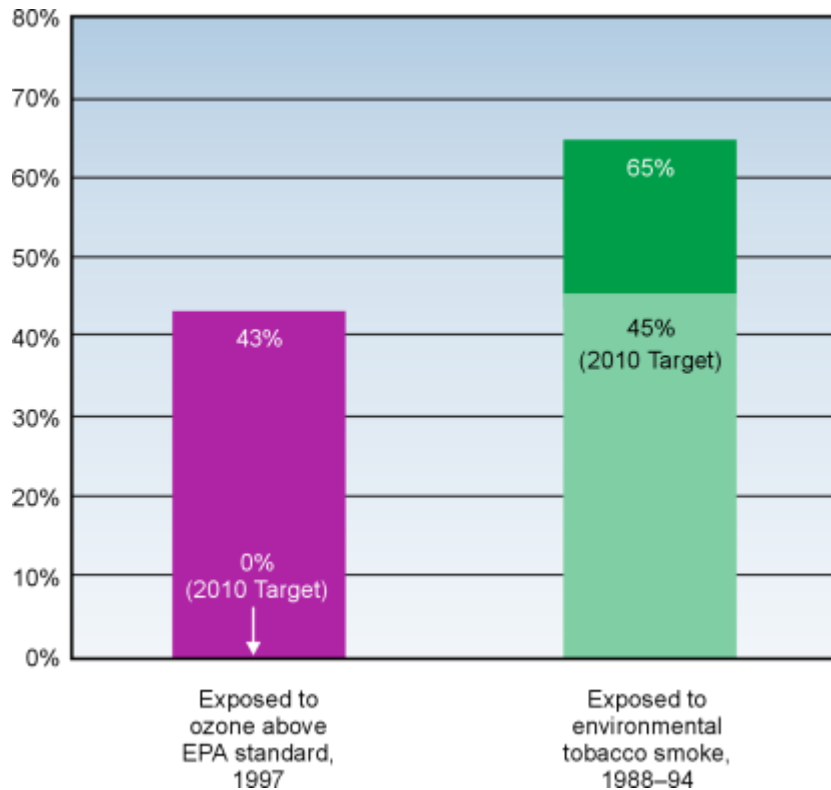
Proportion of Offices in Japan with Tobacco Control



Environmental Quality

Healthy People 2010 Leading Health Indicator

Ozone and environmental tobacco smoke exposure,
United States, 1988–94 and 1997



- Tobacco 27-10. Reduce the proportion of nonsmokers exposed to second hand smoke.



Similar Objectives: Cessation



Cessation—Japan and United States

- Japan:
 - 27% smokers (\geq age 15) want to quit
 - 64% want to reduce # of cigs smoked
- US:
 - Nearly 70% of current smokers want to quit smoking
 - 45% adult smokers try to quit each year
- What works:
 - “Quit-smoking” support from health professionals is key
 - Nicotine replacement therapies (NRTs) double the effectiveness of quitting efforts
 - Quit lines, community support, etc., also work
 - Governments may increase accessibility and affordability of NRTs

How to support quitting smoking

Formulation of a Guideline

MHLW has formulated a guideline that provides not only doctors and nurses but also people in charge of workplace safety and local health services the essential information for educating employees and local people about the relationship of smoking and health

Medical Insurance System

Following the recognition of nicotine addiction as a disease, MHLW has changed the public medical insurance system to cover the medical guidance for nicotine addicts who want to quit smoking (since April 2006), and the use of nicotine patch for controlling nicotine addiction (since June 2006).

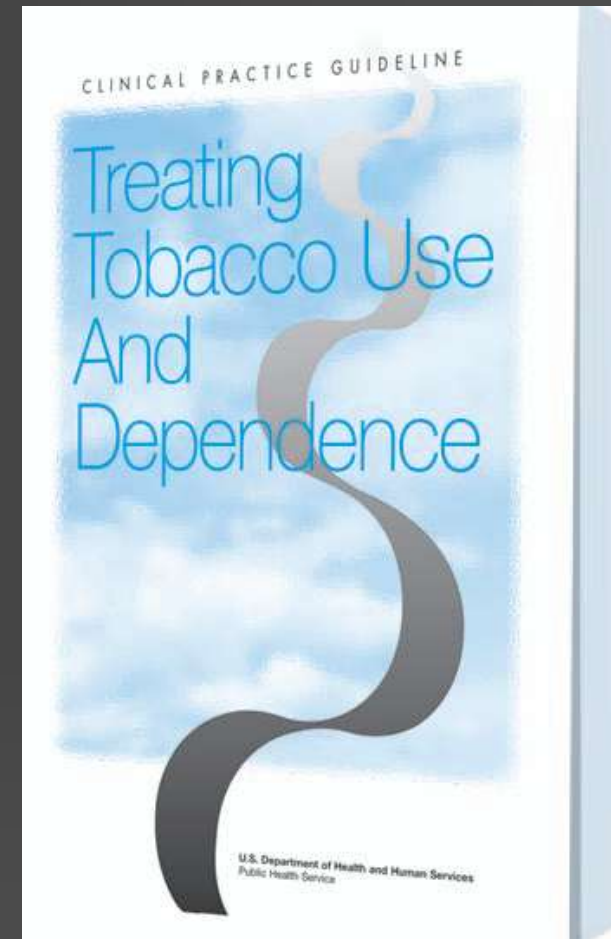
Special Health Guidance

MHLW has forced all the medical insurance providers to offer covered people medical checkups about life-style diseases, including diabetes mellitus, and to implement the special health guidance on the bases of the data.

①Medical checkups include history taking about smoking. ②Smoking history is evaluated as one of the risk factors for brain infarction and cardiac infarction, such as obesity, hypertension, diabetes, and hyperlipidemia. ③Those who have two or more risk factors shall receive health guidance, including how to quit smoking.

Treating Tobacco Use and Dependence

- Sponsored by the Public Health Service
- Provides evidence-based recommendations regarding clinical and systems interventions to increase likelihood of successful quitting
- Updated 2008



Smokefree.gov and 1-800-Quit Now



- Brief tobacco dependence advice and treatment
- Counseling and social support
- Dose-response relationship between intensity of tobacco dependence counseling and its effectiveness

Top National Health Issues

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 - Injury and Violence
 - Environmental Quality
 - Immunization
 - Access to Health Care
-

Approach to Tobacco Control

Health Japan 21

“After this scientific information has been made available to the people of Japan, the basic decision about whether or not to smoking should be left to the free choice of the individual.”

Healthy People 2010

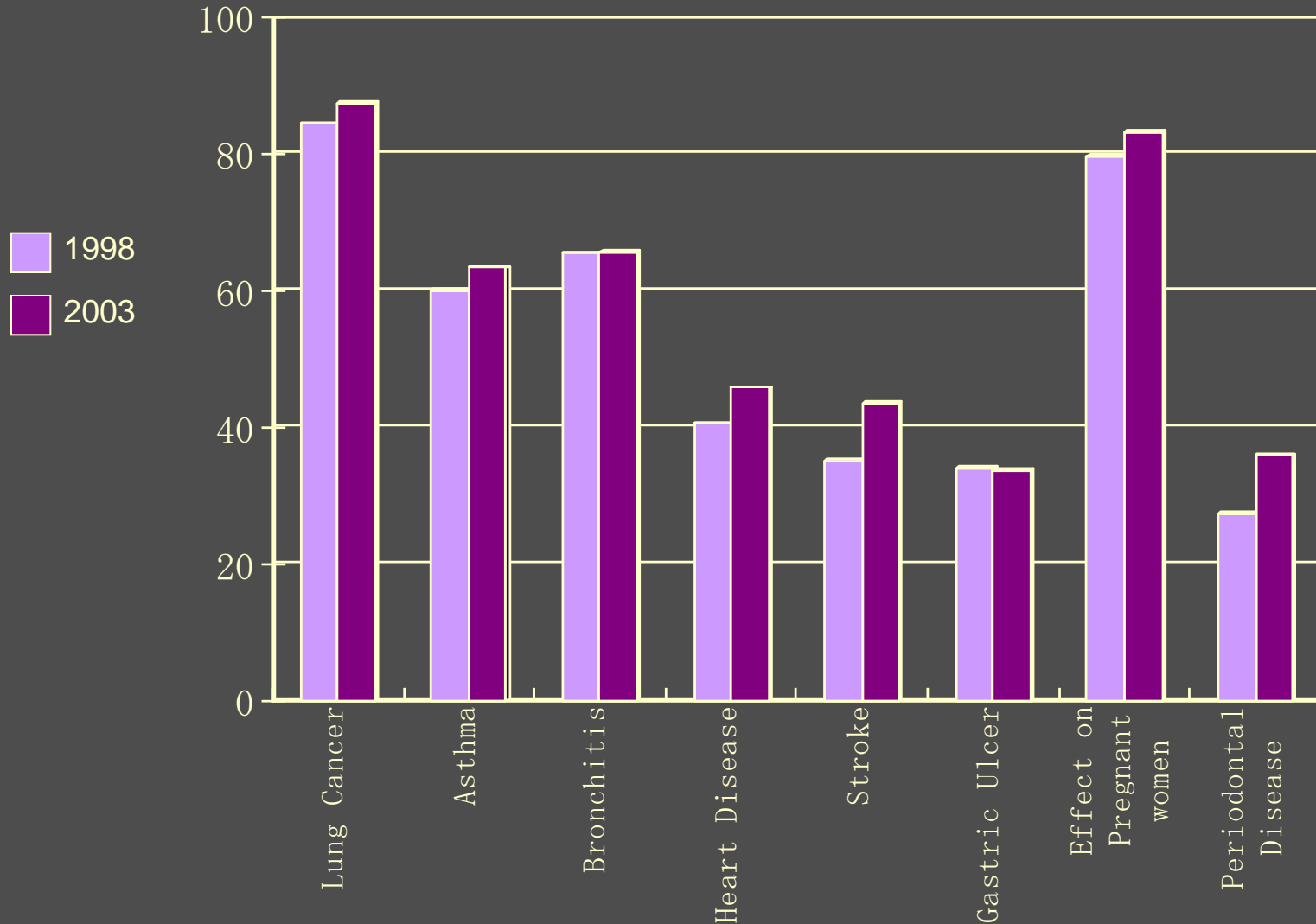
“Comprehensive tobacco control efforts must be further enhanced in order to achieve the U.S. health objective of 12% among adults and 16% among youth by the year 2010.”

Tobacco Control in Health Japan 21

- Raising awareness on smoking and health
 - Website, symposium, packaging & labeling of tobacco products, etc.
 - Preventing minors from smoking
 - The law for prohibiting smoking by minors
 - Financial support to local governments' efforts of tobacco control
 - Protection from exposure to tobacco smoke
 - Article 25 of the Health Promotion law
 - Guidelines of Protection from exposure to tobacco smoke in the workplace
 - Financial support to local governments' efforts of tobacco control
 - Support for smokers who wish to quit
 - Support for smokers who wish to quit smoking in local governments
 - Lecture for local government officials
-

Health Japan 21 Objective: Tobacco

Distribution of knowledge for health effect of smoking: Target 100% for each



National Survey of Smoking and Health (1998), National Survey for Health & Nutrition (2003)

CDC's Best Practices for Comprehensive Tobacco Control Programs

- Comprehensive Tobacco Control Strategies:
 - Prevent the initiation of tobacco use
 - Promote quitting among young people and adults
 - Eliminate nonsmokers' exposure to secondhand smoke.
 - Identify and eliminate the disparities in tobacco use and its effects among different population groups
- Shifted from individual to population-based interventions
 - Community programs
 - Media interventions
 - Policy and regulatory activities
 - Surveillance and evaluation programs

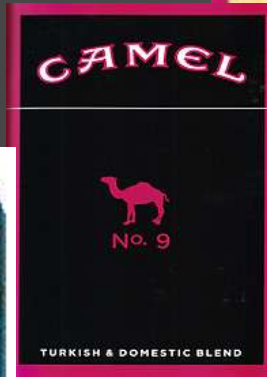


Tobacco Control Challenges: Japan & US

- Eliminate access to minors (i.e. vending machines)
 - Help for people who want to quit
 - Improve smoking cessation for adults, adolescents and pregnant women
 - Better access to cessation therapies, ex, nicotine replacement therapy (NRT)
 - Higher cigarette taxes
 - Consumer information, large clear warning labels
 - Comprehensive bans on cigarette advertising and promotion, or have counter-advertising
 - Regulate content of tobacco products
-

New Tobacco Products and Marketing

- Modified tobacco products
 - (e.g., Omni and Advance)
 - claim to reduce carcinogens
- Cigarette-like products
 - (e.g., Eclipse and Accord)
 - "cigarette" is heated, but not burned
- Oral/smokeless tobacco
 - (e.g., Ariva, Camel Snus, Taboka)
- Camel No. 9 cigarettes
 - Promotional giveaways include berry lip balm, cell phone jewelry, little purses and wristbands, all in hot pink.



WHO Framework Convention on Tobacco Control (FCTC)

“The Convention is a major public health treaty that gives people protection from tobacco for the first time by setting international standards on tobacco price and tax increases, tobacco advertising and sponsorship, labeling, illicit trade and second-hand smoke.”



- Entered into force on 27 February 2005
- 168 countries have ratified the Convention
- Japan is the biggest donor to the FCTC (22% of operating costs)

Contracting Country Obligations

- Forbid sales to minors
- Protect smokers from second hand smoke
- Use taxation to reduce consumption
- Clamp down on smuggling
- Force companies to print larger health warnings on cigarette packs
- Ban advertising and sponsorship promoting tobacco products
- Regulate content of tobacco products



U.S. Food and Drug Administration (FDA) REGULATION OF TOBACCO

- Protecting children
- Protecting public health
- More information for consumers
- Decisions based on sound science

U.S. FDA Protecting Kids from Tobacco

- ~4,000 kids try their 1st cigarette
- 1,000 kids become daily smokers
- FDA issued a final rule, effective June 22, 2010
 - Prohibits the sale of cigarettes or smokeless tobacco to people <18
 - Prohibits the sale of cigarette packages with <20 cigarettes
 - Prohibits distribution of free samples of cigarettes
 - Restricts distribution of free samples of smokeless tobacco, and
 - Prohibits tobacco brand name sponsorship of any athletic, musical or other social or cultural events.





How Can Scientists Inform U.S. Tobacco Control Policy?



FDA Legislation

June 22, 2009: President Obama signs into law the Family Smoking Prevention and Tobacco Control Act

Family Smoking Prevention and Tobacco Control Act

Section 907:

■ 1) SPECIAL RULES.—

“(A) SPECIAL RULE FOR CIGARETTES.—
date of enactment of the Family Smoking Prevention and Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary’s authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

•...a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol)...

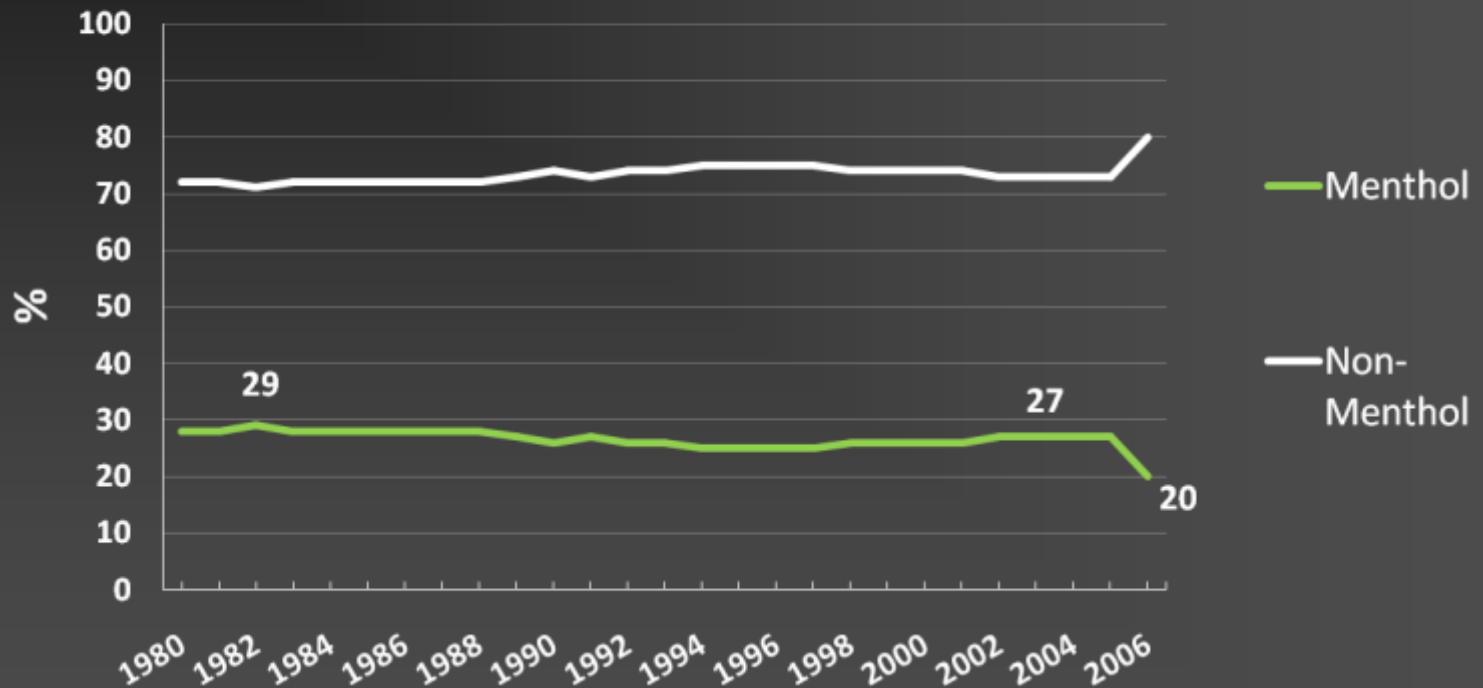
•Nothing in this subparagraph shall be construed to limit the Secretary’s authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

General Facts about Menthol in Cigarettes

- An organic compound naturally found in mint plants like peppermint and spearmint
 - Gives a cooling sensation, and is frequently used to relieve minor pain, irritation and to prevent infection
 - About 90% of cigarettes marketed in the U.S. contain menthol
 - “mentholated” cigarettes contain amounts that are 0.1%-0.45% of the tobacco weight
 - “non-mentholated” cigarettes contain amounts that are 0.01%-0.03% of the tobacco weight
 - First menthol cigarette brand, 1930’s Spud
 - Actively marketed to consumers based on its physiological effects
 - Anti-irritant, cooling agent
 - Research of industry documents show history of marketing to women, youth and minority groups
 - African Americans may be most directly targeted group
 - Exclusively menthol cigarette brands include: Kool, Newport and Salem
-

Menthol Use & Tobacco Industry

Domestic Market Share of Menthol & Non-menthol Cigarettes, 1980- 2006



- 20% of market share (previously 27%)

Who Smokes Menthol Cigarettes?

- 27% (approximately 11 million people) of current smokers
- 32% of female smokers
- 31% of young adult smokers ages 18- 24
- 58% of menthol smokers are White
- Nearly 70% of African American smokers



Family Smoking Prevention and Tobacco Control Act

Section 907:

■ (e) Menthol Cigarettes. —

- (1) REFERRAL; CONSIDERATIONS.—Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee under section 917(a), the Secretary shall refer to the Committee for

•...the Secretary shall refer to the Committee for report and recommendation...the issue of 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...

under section 917(c)(4), the issue of the impact of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in paragraph (2).

(2) REPORT AND RECOMMENDATION.—Not later than 1 year after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

- (3) RULE OF CONSTRUCTION.—This section shall be construed to limit the Secretary's authority under this section or other sections of this Act.

•Not later than 1 year after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations...

Tobacco Products Scientific Advisory Committee (TPSAC):

- The Tobacco Products Scientific Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to the regulation of tobacco products.
 - The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information and recommendations to the Commissioner of Food and Drugs.
-

TPSAC cont.

- *Who:*
 - 12 members, including the Chair
 - 9 voting (7 health care professionals, 1 govt. and 1 public representative)
 - 3 non-voting (industry interests – manufacturing, growing, small business)
- *What:*
 - “provide advice, information, and recommendations to the Commissioner of Food and Drugs on health and other issues relating to tobacco products”
- *When:*
 - ~4 meetings
- *Why:*
 - Report on the impact of the use of menthol in cigarettes on the public health
- *How (we can impact):*
 - An academician or a practitioner member uses his or her expert knowledge to provide state-of-the-art advice on scientific issues under deliberation at the FDA. These representatives publicly explore scientific questions that have regulatory impact.

TPSAC: What is menthol's role?

- HHS Required report “Impact of the Use of Menthol in Cigarettes on the Public’s Health”
 - Demographic Patterns
 - Sensory Qualities and Topography
 - Advertising and Consumer Perceptions
 - Smoking Initiation
 - Nicotine Dependence
 - Smoking Cessation
 - Potential Health Effects of Menthol
-

2nd Conference on Menthol Cigarettes

Washington, DC October 19-20, 2009
American Legacy Foundation, CDC

■ Day 1: Evidence

- Increase intensity of smoking
 - Increase permeability of human tissue → increased exposure
 - Increase in carcinogenesis pyrolysis products
 - Affects metabolism of nicotine
 - Increase addictiveness of tobacco
 - Increase absorption of nicotine
-

2nd Conference on Menthol Cigarettes

- Day 2: Success Stories
 - Combating advertising
 - Industry tactics
 - Increasing knowledge & awareness
 - Help smokers change their media environment
 - Issues
 - Stores are pressured to sell cigarettes
 - Need more information about menthol smoking
 - Don't know enough about switching
 - Do not have brand information
 - Need to phenotype smokers
-

Conference Summary

- Focusing on youth is a better strategy
- Enough evidence to call for banning menthol
 - Increased uptake
 - Advertising
 - Cessation difficulty
- FDA should demand tobacco industry to release its data on menthol to FDA

TReND: Menthol Journal Supplement

■ **Correlates/Patterns:**

- Mentholated Cigarette Smokers in the US: National Patterns & Correlates
- Associations Between Menthol Cigarette Smoking & Smoking Characteristics
- Demographic & Socioeconomic Differences in Smoking Patterns Among Menthol & Non-menthol Smokers
- Impact of Sociodemographic Factors, Menthol/Non-menthol Cigarette Use, & State Tobacco Control Policies on Smoking Behaviors in Young Adult Smokers in the TUS-CPS
- A Bio-psycho-socio-cultural Examination of Menthol Smoking

■ **Co-occurring Risk Factors & Diseases:**

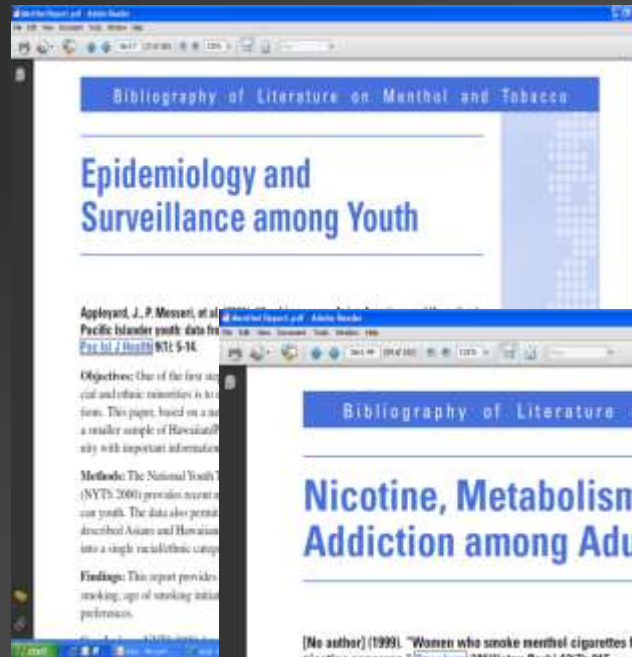
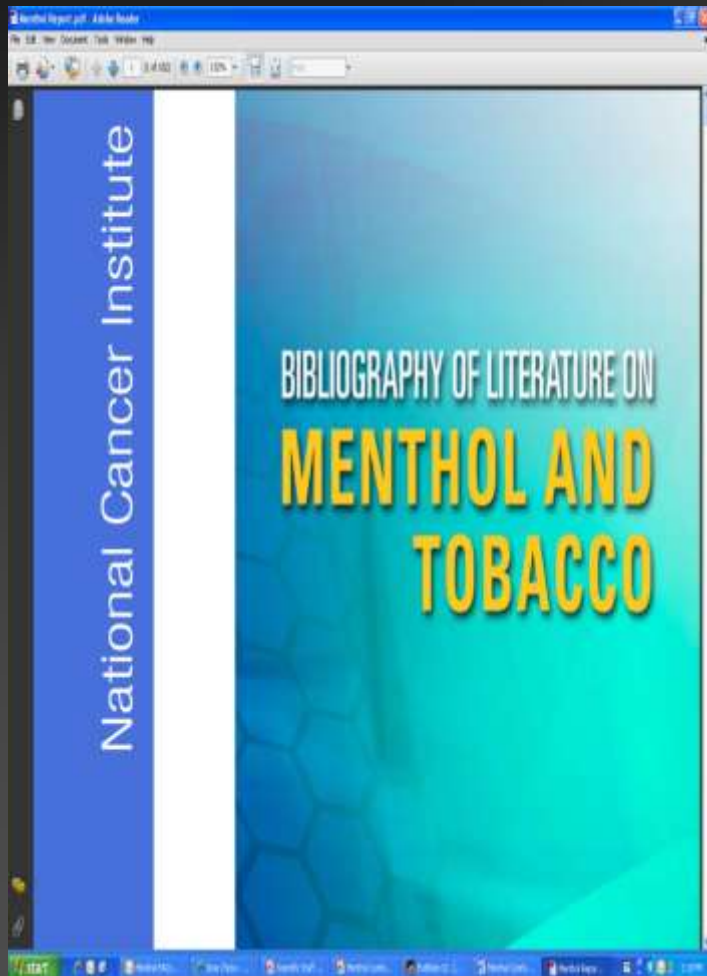
- Health risk Profiles of Menthol Versus Non-Menthol Smokers

Journal Supplement (cont.)

■ Dependence & Cessation:

- Nicotine Dependence & Quitting Behaviors among Menthol & Non-menthol Smokers with Similar Consumptive Patterns
 - Menthol Cigarettes, Smoking Cessation, & Utilization of Evidence-based Tobacco Cessation Treatment
 - Menthol Cigarette Smoking & the Cessation Process across Racial/Ethnic Groups in the U.S.
 - Quit Attempts & Sustained Quit among Menthol & Non-menthol Smoking Women
 - Demographic, Social & Occupational Influences on Quitting Behaviors of Menthol Smokers
 - Workplace Smoking Restrictions, Cessation Services & Menthol Cigarette Use
-

NCI Bibliography on Menthol



Proactively Informing US Tobacco Policy

- Federal Register
 - TPSAC and other FDA advisory committee meetings
 - FDA draft Guidance, Compliance Regulatory Information
 - National surveys on tobacco use
 - Adhere to deadlines
- Next TPSAC meetings (7/16-16)
 - Scientific reviews
 - Presentations during open comment
 - Comments submitted to the open docket
 - Anticipate FDA's scientific needs
- Special Government Employee (SGE)



Public Comments to FDA Dockets

- Association for the Treatment of Tobacco Use and Dependence (ATTUD) and the Society for Research on Nicotine and Tobacco (SRNT) - Citizen Petition
 - Docket No. FDA-2010-P-0089
 - Change regulation of NRT products
 - Expand access to NRT
- Impact of Dissolvable Tobacco use on Public Health
 - Docket No. FDA-2010-N-0123
 - How should FDA regulate dissolvable smokeless tobacco
- Tobacco Product Advertising and Promotion to Youth and Racial and Ethnic Minority Populations
 - Docket No. FDA-2010-N-0207
 - Advertising and promotion of menthol and other cigarettes to youth in general, and to youth in minority communities.



Summary

- Tobacco is a global public health priority
 - Japan and U.S.
 - Similar health priorities
 - Different approaches to tobacco control
 - Similar tobacco control challenges
 - New Tobacco Control Act is an important part of the U.S. Comprehensive Tobacco Control
 - Researchers can inform tobacco policy with science
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