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Tobacco Control Strategies II

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Section A

Comprehensive Approach

Comprehensive Tobacco Control Programs

- Research has shown that large-scale, sustained programs which include community-based activities are effective in reducing tobacco use
- Diverse, interested parties sit down and plan together to maximize potential impact
- Activities address the problem in multiple ways

Comprehensive Tobacco Control Programs

- Comprehensive tobacco control efforts involve
 - Changing social norms
 - Changing attitudes toward tobacco use
 - Changing the environment
 - Changing policy
 - **A team of committed individuals working together**

Comprehensive Tobacco Control Programs

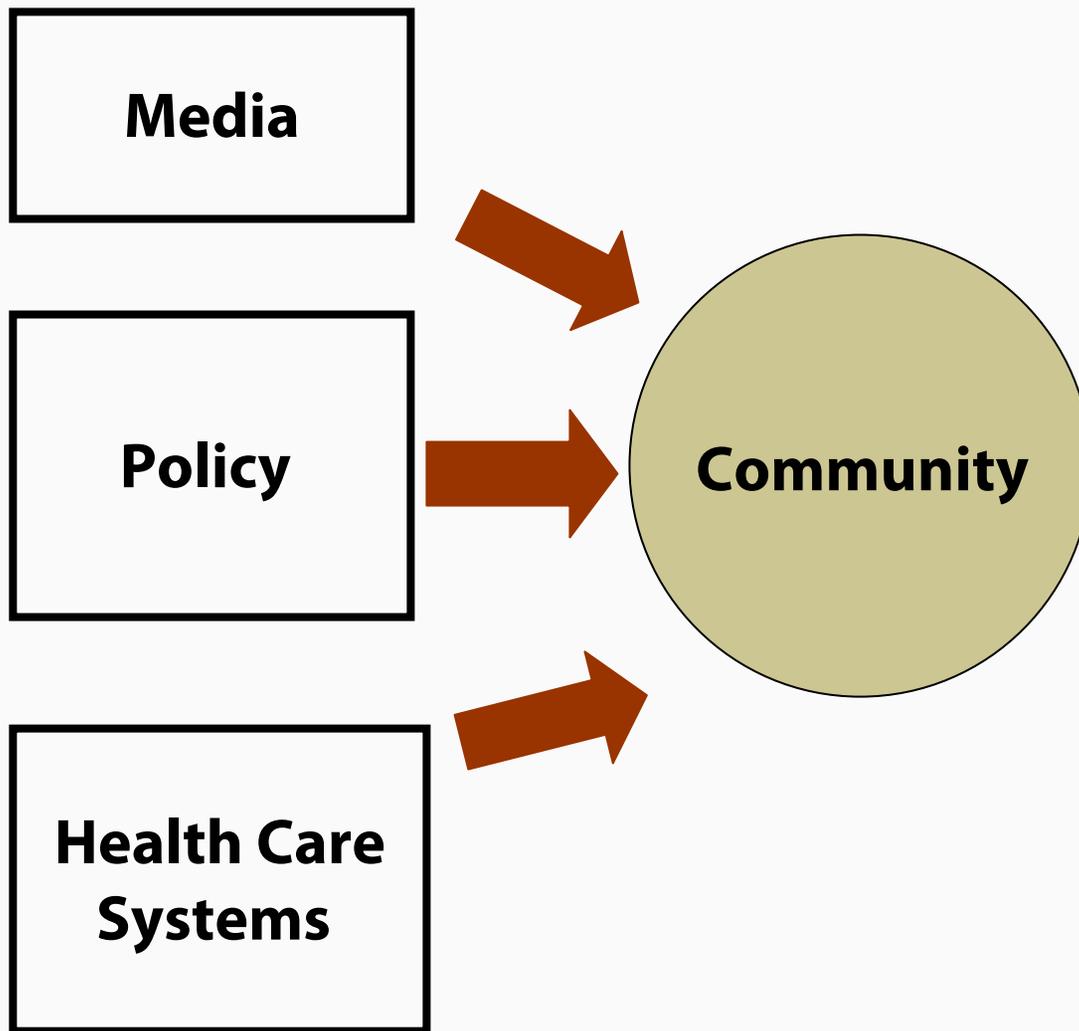
- Tobacco-free schools, worksites, and public places
- Coordinated school health programs with tobacco use prevention
- Strong support for high taxes on tobacco products
- No sales of tobacco to minors
- Cessation services for those wanting to quit
- Restrictions on tobacco ads and promotions
- Ongoing public health education campaigns to change opinions and norms about tobacco use
- Ability to identify and counter tobacco industry influence/involvement

Comprehensive Tobacco Control Programs

- New York State Tobacco Control Program (NYTCP) strategies
 - Community mobilization
 - Cessation
 - Media and counter-marketing
 - ▶ Supported by evaluation and research

Comprehensive Tobacco Control Programs

- New York State tobacco cessation strategies



Comprehensive Tobacco Control Programs

- New York State Tobacco Control Program
 - Media
 - ▶ TV, radio, print, out-of-home
 - ▶ Promotes both general cessation messages and *Quitline*
 - Policy
 - ▶ Price
 - ▶ Clean indoor air policies
 - Cessation Resources
 - ▶ New York State Smokers' Quitline
 - ▶ Cessation centers
 - ▶ Medicaid coverage of pharmacotherapy

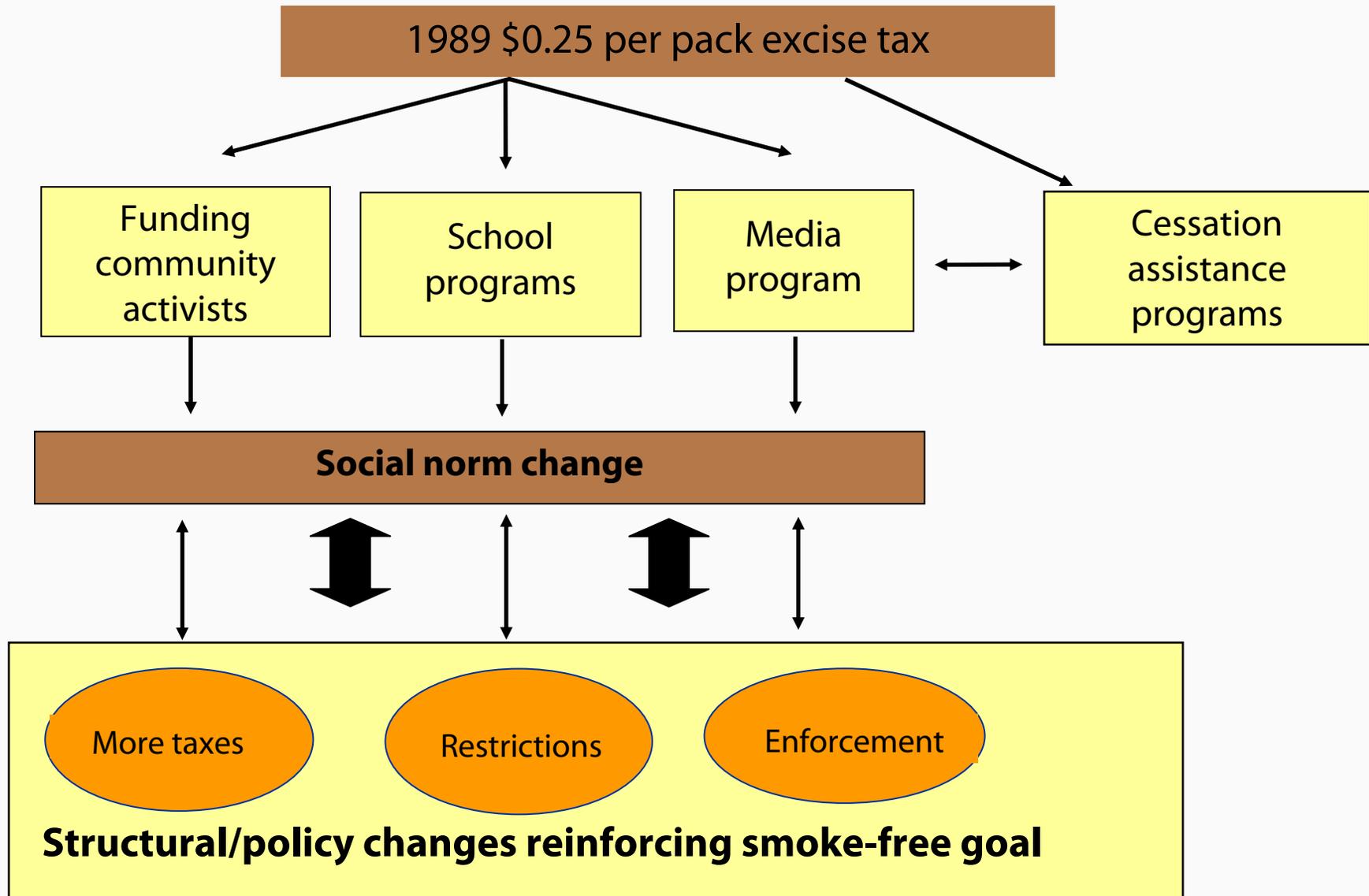
- NYC Clean Indoor Air Act
 - Went into effect July 24, 2003
 - Expanded the city's 1995 Smoke-Free Act
 - Prohibited smoking in ALL indoor areas, including—
 - ▶ All places of employment
 - ▶ Bars
 - ▶ Restaurants
 - ▶ Public transportation, including all ticketing, boarding and waiting areas and in buses, vans, taxicabs, and limousines
 - ▶ All schools, colleges, universities, vocational institutions—public and private
 - ▶ Hospitals and residential health care facilities

- Violations (of the NYC Clean Indoor Air Act) subject to fines up to \$2,000
- Part of a comprehensive tobacco control program (high taxes on tobacco products, advertising restrictions, Quitline, medical coverage for cessation products, etc.)

Comprehensive Tobacco Control Programs

- First NYC-CIAA evaluation
 - A decline in New York's per capita cigarette consumption faster than the national average
 - A steady decline in the rates of secondhand smoke exposure both in the home and in the workplace
 - Very high compliance (92.9%) with the Clean Indoor Air Act

The California Tobacco Control Program



The California Tobacco Control Program

- The media campaign of the California Tobacco Control Program was designed to affect community norms by non-saturation advertising focused on—
 - Attacking the corporate image of the tobacco industry
 - Emphasizing the dangers of secondhand smoke
 - Attacking the supply of cigarettes to minors
 - Emphasizing the health consequences of smoking
 - Promoting smokers to seek help to quit

The California Tobacco Control Program

- California
 - Cigarette consumption down by 38 percent
 - Adult smoking down from 27 percent to 18 percent
 - Children with secondhand smoke in the home down from 27 percent to 13 percent

“The potential for combined effects underscores the need for comprehensive approaches.”

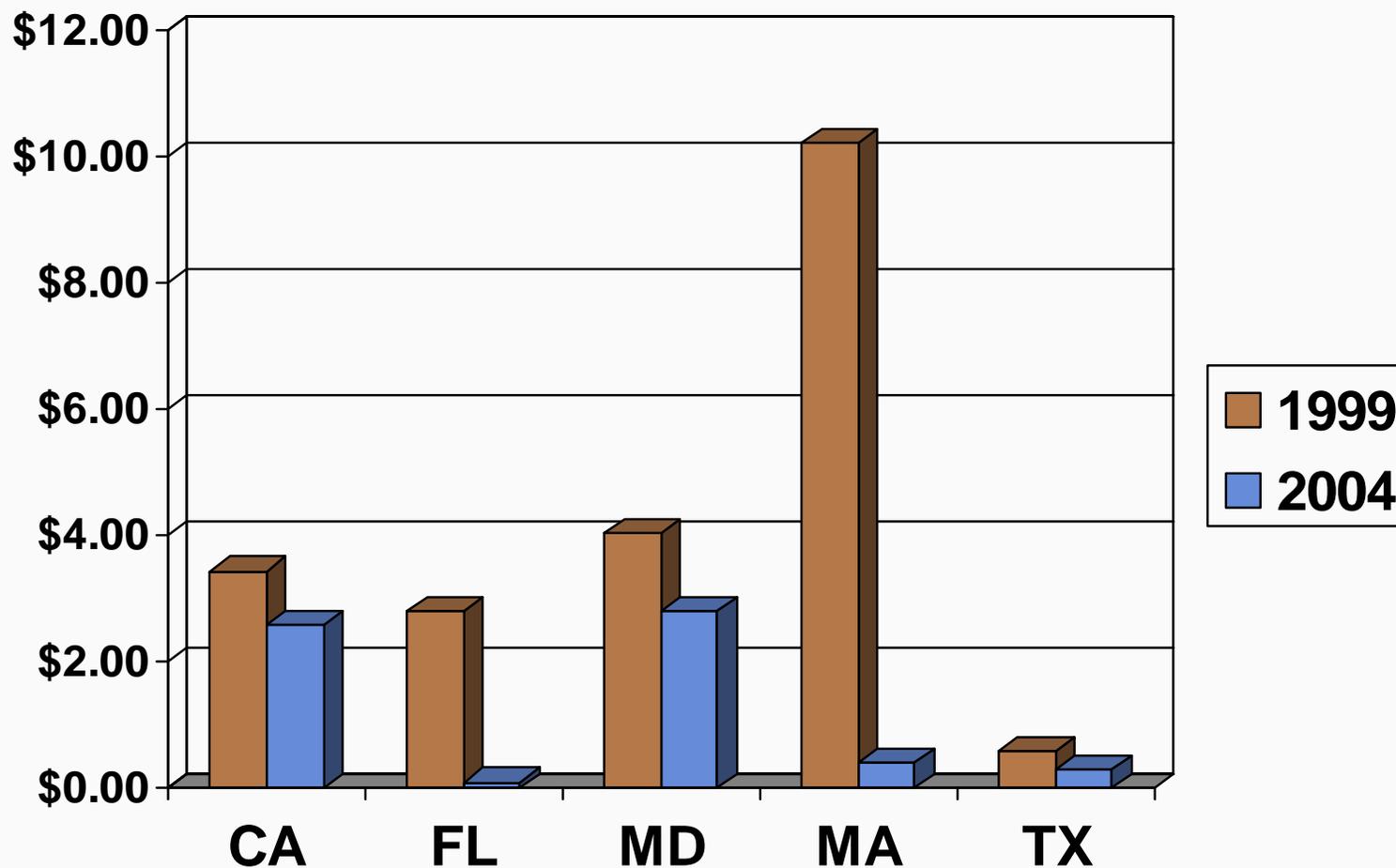
*—Reducing Tobacco Use:
A Report of the Surgeon General
August 2000*

Comprehensive Tobacco Control Programs

- Comprehensive tobacco control programs require substantial funding
 - Dose-response relationship between levels of spending and program effect
 - Increase in per capita spending is associated with larger tobacco control program effect
 - Increased efficiency from lessons learned

Comprehensive Tobacco Control Programs

State Per Capita Funding for Tobacco Control (1999 and 2004)

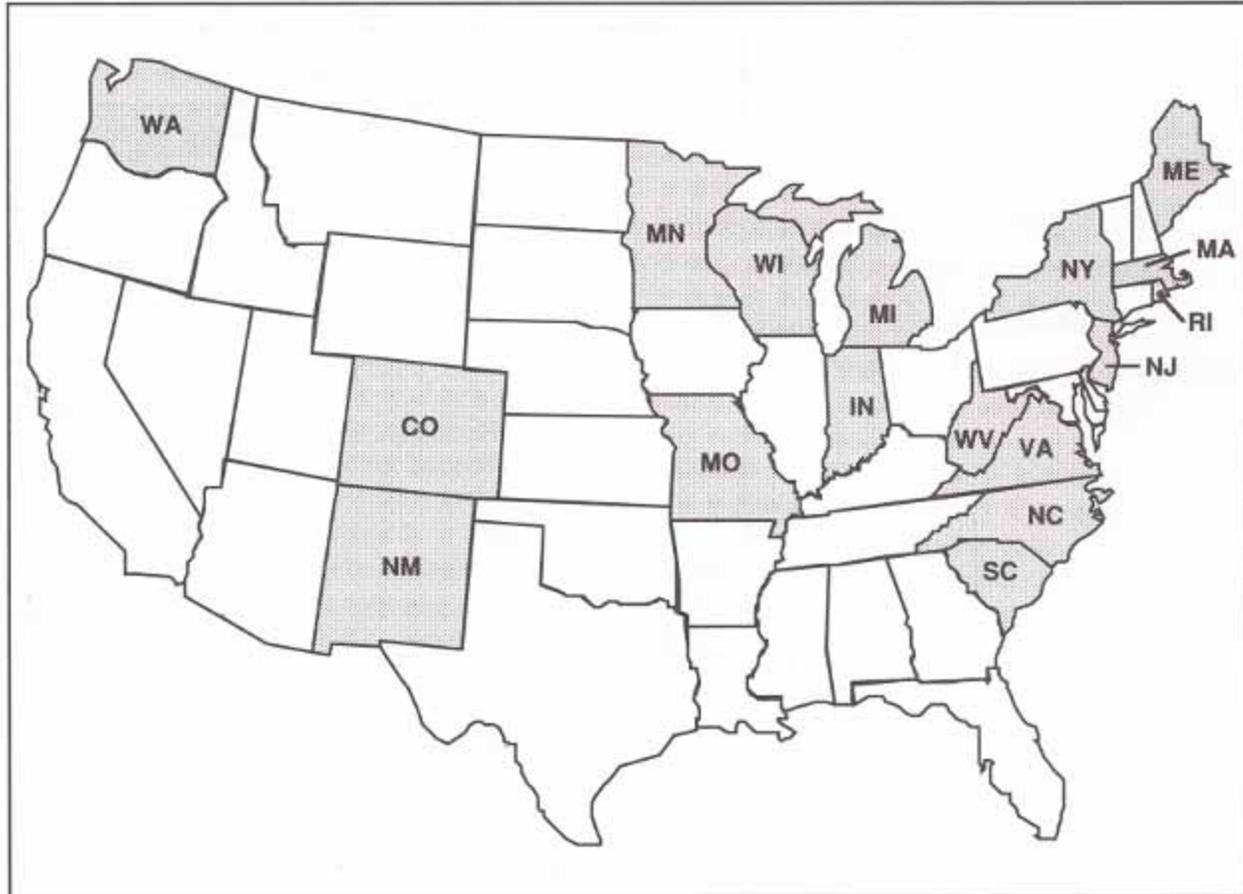


American Stop Smoking Intervention Study (ASSIST)

- In October 1991, the National Cancer Institute awarded 17 state health departments contracts to deliver tobacco control
 - Principal focus of the program was to build state infrastructure to deliver tobacco control and alter the environmental factors associated with tobacco use
 - States received \$1,142,000 on average from 1993–1999

American Stop Smoking Intervention Study (ASSIST)

ASSIST states



Source: ASSIST - Shaping the future of tobacco prevention and control. Monograph 16, NCI Tobacco Control Monograph Series. US Department of Health & Human Services, National Institutes of Health, National Cancer Institute. <http://dccps.cancer.gov/tcrb/monographs/16/index.html> accessed 2/28/06

- Focused on—
 - Increasing taxes and indoor air laws
 - Reducing advertising and youth access
 - Developing advocacy tools for policy and media
 - Education
 - Developing the infrastructure for tobacco control in many states

What Was Done to Evaluate ASSIST?

- Developed a conceptual framework and identified the pathways to link inputs to outcomes
- Focused on research questions starting with assessing ASSIST status and moving on to assessing overall tobacco control efforts
- Developed new exposure measures to assess state-level factors (Strength of Tobacco Control, Initial Outcome Index)

- ASSIST states had a greater decrease in adult smoking prevalence (than non-ASSIST states)
- ASSIST states that experienced greater improvement in anti-tobacco policies had larger decreases in per capita cigarette consumption (the average number of cigarettes consumed per person per month in each state)
- States with greater “capacity,” or ability to implement tobacco control activities, had lower per capita cigarette consumption



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Section B

Product Regulation

- Tobacco is *NOT* regulated by the FDA
 - 1820—U.S. Pharmacopoeia (USP), first official compendium of drugs in the United States; nicotine is listed
 - 1898—The Industry drops nicotine from the list
 - 1906—FDA established; first attempt to regulate drugs
- Tobacco also excluded from the jurisdiction of—
 - The Fair Packaging and Labeling Act of 1966
 - The Controlled Substances Act of 1970
 - The Consumer Product Safety Act of 1972
 - The Toxic Substance Act of 1976

The FDA's Efforts to Regulate the Industry

- FDA efforts to regulate the cigarette industry
 - August 1995—Clinton administration proposes FDA regulations to restrict youth tobacco access. Tobacco industry sues
 - 1995—Nicotine defined as a drug and cigarettes defined as drug-delivering devices using the FDA definition: “an article other than food intended to effect the structure or function of the body”
 - August 1996—FDA regulations take effect

The FDA's Efforts to Regulate the Industry

- April 1997—A federal court rules that FDA has authority to regulate tobacco but not to restrict tobacco advertising. Appeals are filed
- August 1998—U.S. 4th Circuit Court of Appeals overturns a lower court; rules that FDA had gone beyond the intent of Congress
- March 2000—Supreme Court rules 5–4 against FDA regulation. The FDA does not have the power to regulate nicotine as a drug and cigarettes as drug delivery devices

- *"Congress . . . has created a distinct regulatory scheme for tobacco products, squarely rejected proposals to give the [FDA] jurisdiction over tobacco, and repeatedly acted to preclude any agency from exercising significant policy-making authority in the area"*—Justice Sandra Day O'Connor

- **March 17, 2005**—U.S. Senators Mike DeWine (R-OH) and Edward Kennedy (D-MA) and U.S. Representatives Tom Davis (R-VA) and Henry Waxman (D-CA) introduced identical, bipartisan bills in Congress to grant the U.S. Food and Drug Administration (FDA) authority to regulate tobacco products
 - Require reduction or elimination of harmful chemicals to make them less harmful or less addictive
 - Prohibit health claims about so-called "reduced risk" tobacco products
 - Prohibit terms such as "light," "mild," and "low-tar"
 - Require the disclosure of the contents of tobacco products and tobacco industry research about the health effects of their products
 - Require larger and more informative health warnings on tobacco products

- 1999—International regulation meeting in Berlin
 - *“the time now has come for concerted regulation of tobacco products”*—WHO Director-General, Dr. Gro Harlem Brundtland
- FCTC Article 9—Regulation of the content of tobacco products
 - International network on tobacco testing and research for regulation (INTTARR) is formed
- FCTC Article 10—Regulation of tobacco product disclosures
 - Canada and Thailand require full disclosures

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- Absent meaningful FDA authority over tobacco products, "reduced risk" health claims become a new marketing tool for the tobacco industry to hook new customers



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Section C

Litigation

- Why Litigation?
 - No FDA regulation
 - No Congressional action
 - Courts offer an alternative

- Recoupment of costs states paid to treat ill smokers
- Antitrust law violations
- Violation of consumer protection laws
- Conspiracy to withhold information about adverse health effects of tobacco
- Manipulation of nicotine levels to keep smokers addicted

Litigation—Compensatory Damages Cases

- Tobacco products liability suits offer at least six potential social benefits—
 1. Raise the cost of tobacco products
 2. Draw public attention to the dangers of smoking
 3. Can motivate industry change
 4. Unearth incriminating internal documents through discovery
 5. Money from verdicts can be used to reimburse health-care costs
 6. A flood of cases could bankrupt the industry

- Brought in 1983 by Rose Cippolone, a 40-year smoker with lung cancer
- Claim was “failure to warn” smokers of the risks of smoking
- Award (first) made for \$400,000 (for pre-1986)
- Pre-emption by “Cigarette Labeling Act”

■ **Flight attendants**

- Filed in 1991 by Stanley and Susan Rosenblatt
- A class-action suit on behalf of flight attendants
- Sought damage for diseases and deaths caused to flight attendants by exposure to secondhand tobacco smoke in airplane cabins
- The settlement included \$300 million for the establishment of a not-for-profit medical research foundation (FAMRI)

- Filed in **1994** by Susan and Stanley Rosenblatt
- Key class action lawsuit in Florida
- Class—all addicted smokers in Florida
- Awarded \$145 billion judgment to Florida smokers
BUT
- Class decertified in Florida District Court

- What is “decertification”?
 - The court notes that there were differences in how the jury regarded each of the representative class members' illnesses and experiences as different
 - The court knew that everyone's experience with smoking-caused disease was not identical in 1996. The Court suggests that the better approach would be to review individual cases
 - The court says, "it would further be unjust to bind absent class members to a negative decision where the class representative's [sic] claims present different individual issues than those of the absent members."

- Master Settlement Agreement, 23 November 1998
 - Settled state lawsuits against tobacco industry
 - Extends to 46 states (four states settled individually)
 - Provides \$206 billion to states over 25 years
 - Limited public health provisions
 - No funds specifically earmarked for tobacco control

- Brought in state of Illinois in 2001
- Class—persons who smoked selected “light” brands of cigarettes
- Claim for fraud and recovery of costs
- Philip Morris, Inc. ordered to pay **\$7.1 billion in compensatory damages and another \$3 billion in punitive damages**

- Proved that Philip Morris intentionally manipulated the design of its so-called "light" cigarettes
- By placing the words "lowered tar and nicotine" on every pack of Marlboro Lights cigarettes, Philip Morris effectively committed fraud each time a consumer purchased them
- There is a widespread belief that "light" means a product contains less of an unhealthy ingredient. In this case, smokers bought Marlboro Lights because they thought those cigarettes contain less tar and nicotine

Government allegations—

- False statements denying that smoking and SHS cause disease
- False statements denying that cigarettes are addictive
- Marketing to youth
- Manipulating nicotine in cigarettes to ensure addictiveness and disseminating false statements denying that marketing
- Marketing “light” and “low tar” cigarettes as less hazardous despite knowing that they are not



Judge Kessler

Litigation—Department of Justice (DoJ) Trial

- Relief sought by the government—
 - Monetary relief
 - ▶ “Disgorgement” of \$280 billion of defendants’ past proceeds
 - Nonmonetary relief
 - ▶ Prohibitory injunctions (i.e. making false or misleading statements about cigarettes, youth marketing, etc)
 - ▶ Disclosure of documents concerning health risks and addictive nature of smoking
 - ▶ Mandatory corrective statements about the health risks of smoking and the addictive properties of nicotine in future marketing campaigns
 - ▶ Funding of remedial programs (research, public education campaigns, medical monitoring programs, smoking cessation programs)

Litigation—Department of Justice (DoJ) Trial

Government's
racketeering case
against tobacco
companies wraps up its
first phase
- The New York Times

Tobacco profits
ruled safe from
federal seizure
- Baltimore Sun

For a trial lacking in
drama, a star witness,
of sorts
- The New York Times

Appellate court backs
companies in tobacco
case
- The New York Times

- **Araki vs. Japan Tobacco Corporation (October 2003)**
 - Tokyo District Court ruled—
 - ▶ That there is a “socially well-understood awareness of the risks of harm associated with cigarette smoking.” The court recognized only that smoking caused an “increased risk” for lung cancer and other illnesses,” but other causes could have been responsible for the plaintiffs’ cancers”
 - ▶ That “tobacco smoking is addictive, but only mildly so, such that one can easily quit by the exercise of individual will.” The court expressly ruled that the addictiveness of tobacco is less severe than the addictiveness of alcohol or illegal drugs

Litigation in the 21st Century and Beyond

- Litigation is likely to spread world-wide, raising consciousness of the dangers of tobacco use, exposure to tobacco smoke, and of the nefarious role played by cigarette manufacturers—even in countries where tobacco use and marketing is currently uncontroversial
- Litigation will be increasingly used by NGOs to force governments and tobacco companies to take existing laws seriously and to obtain judicial orders making public places smoke-free
- NGOs and health departments will become increasingly adept at drafting laws that can withstand industry legal attacks and defending them when these attacks arrive