

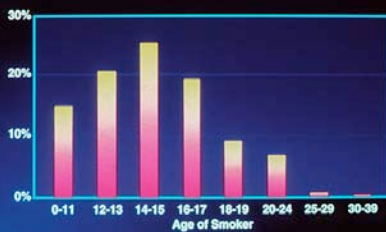
Evolution of Tobacco Law

John Wargo, Yale University
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Environmental Politics and Law
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“...if we are to attract the nonsmoker, or pre-smoker, there is nothing in this type of product that he would currently understand or desire...instead we somehow must convince him with wholly irrational reasons that he should try smoking.”

R.J. Reynolds

Most Smokers Begin as Teens



Source: US Centers for Disease Control and Prevention

POPULAR MILDNESS ADVERTISING DEVICES

POPULAR MILDNESS ADVERTISING DEVICES

“THEY DON'T GET YOUR WIND”
ATHLETES SAY

The mild cigarette the athletes smoke is the mild cigarette for YOU!

SO MILD YOU CAN SMOKE ALL YOU WANT!

Camels COSTLER TOBACCO'S!

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US National Cancer Institute:
28 Carcinogens
3-4 X Nicotine

Who Uses It?
7.9 Million Americans

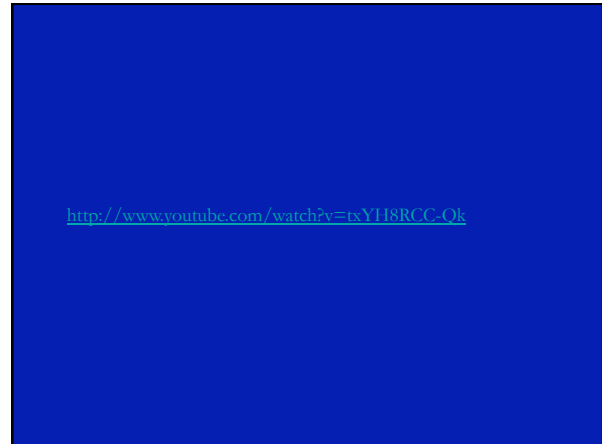
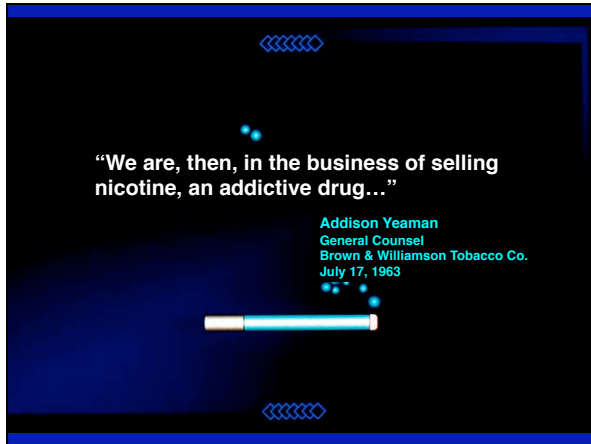
<http://www.cancer.gov/cancertopics/factsheet/Tobacco/smokeless>

Rich Sender, who developed oral cancer at age 24



About 25% of children aged 3–11 years live with at least one smoker.

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**Beyond Nicotine:
Other Hazardous Chemicals in Tobacco Smoke**

Nitrosamines; tar; pesticides; carbon monoxide; volatile organic compounds (benzene, for example); metals (such as cadmium and radioactive polonium); carbonyl compounds; and polycyclic aromatic hydrocarbons.

101 Pesticides Used on Tobacco

1	Styrenesulfonic sulfite (1:3)	35	alkyl alcohol	69	mg phosphate
2	Sulfuric acid, copper 2+ salt basic	36	aluminum phosphide	70	malathion
3	Tobacco copper sulfate monohydrate	37	bertholite	71	mancozeb
4	Tobacco copper sulfate	38	beryllium	72	malathion
5	Aluminum salts of C8-18 and C19 fatty acids	39	carbaryl	73	methidathion technical
6	Phenylacetylene	40	carbonyl	74	methidathion
7	Ethoxypp	41	Chain	75	methidathion
8	Malic Hydroxide potassium salt	42	chlorpyrifos	76	methidathion
9	Dymol	43	chlorpyrifos	77	methidathion
10	Diazinon (potassium) hydrotreated light paraffinic	44	cis-9-octadecenoic acid	78	methyl formate
11	Diazinon (potassium) hydrotreated heavy paraffinic	45	oxymer	79	acetone
12	Diazinon (potassium) solvent-refined light paraffinic	46	copper ethoxide hydroxide	80	mg/254
13	Diaz (gas), alkyl, oil, light naphthene	47	copper ethoxide hydroxide	81	malathion
14	Nitrocellulose (potassium) diethyl sepiol	48	copper sulfate	82	metoprolol
15	Solvent (potassium) diethyl sepiol	49	oil oil	83	oxalic acid, copper salt
16	Potassium bicarbonate	50	oxymer hydroxide	84	acetone
17	Potassium borate	51	oxymer oxide	85	potassium
18	Pyrethrin	52	cyhalothrin I	86	potassium
19	Lapicide A	53	dimethyl	87	potassium
20	Tetrahydroxy acetate	54	dimethyl	88	potassium
21	Tetrahydroxy acid	55	dichloroacetic	89	phosphorus
22	Nitrocellulose	56	dichloroacetic	90	potassium
23	Nitrocellulose A	57	dichloroacetic	91	potassium
24	2',3',4',5'-Tetrahydroxyacetate	58	dichloroacetic	92	potassium
25	Carb. Fertilizer	59	dichloroacetic acid	93	potassium
26	Endosulfan (technical form)	60	endosulfan	94	potassium
27	Potassium acid	61	ethanol	95	potassium
28	Dichloroacetic	62	ethanol	96	potassium
29	1-decanol	63	ethanol	97	potassium
30	1-hydroxyacetone	64	ethanol	98	potassium
31	1,3-dichloropropane	65	ethanol	99	potassium
32	nitrocellulose	66	fluorinated	100	Thiobenzamide
33	nitrocellulose	67	glycolic acid	101	Urea
34	nitrocellulose	68	nicotinyl butyric acid		

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Increase Nicotine Content by Adding Nicotine to Filters, Wrappers, etc.

Patent No. Date	Description	Assignee
3,280,823 10/25/66	Increase nicotine content in the tobacco smoke by use of a nicotine-ion exchange placed in the filter.	Phillip Morris Incorporated
3,584,630 6/15/71	Increase nicotine content in the smoke of a tobacco product by adding nicotine to carbon black in filter.	Phillip Morris Incorporated
5,105,834 4/21/92	Add tobacco extract containing nicotine to the filter of cigarettes.	R.J. Reynolds Tobacco Company
4,676,259 6/30/87	Device to deliver increased nicotine by applying nicotine solution to the filter.	Advanced Tobacco Products Inc.
4,236,532 12/02/80	Method of producing a wrapper for a smoking rod which has screen printed on it, among other things, a "physiologically active agent" such as nicotine.	Gallaher Limited

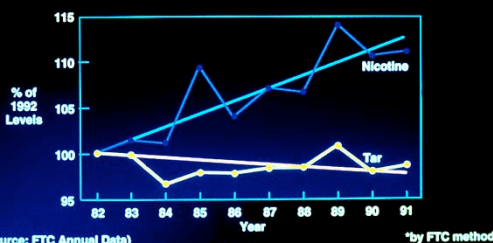
Increase Nicotine Content by Adding Nicotine to Tobacco Rod

Patent No. Date	Description	Assignee
3,109,436 11/05/63	Increase nicotine content of smoke tobacco by adding a composition of nicotine-ion exchange resin directly to tobacco.	Abraham Bayley and Frank E. Resnik
4,215,706 8/05/80	Process to transfer nicotine from a tobacco source to a nicotine-deficient tobacco, reconstituted tobacco or tobacco filler material.	Loew's Theatres, Inc.
4,830,028 5/16/89	Increase nicotine content of smoke by adding nicotine and an organic acid (nicotine levulinate salt) to the cigarette.	R.J. Reynolds Tobacco Company
4,836,224 6/06/89	Make high nicotine smoke less harsh by adding an organic acid additive to tobacco.	R.J. Reynolds Tobacco Company
5,031,646 7/16/91	Make high nicotine smoke less harsh by adding an organic acid additive to tobacco.	R.J. Reynolds Tobacco Company
3,861,400 1/21/75	Increase nicotine content of smoke by adding complexes of nicotine and galacturonic acid or polymannuronic acid to tobacco.	Imperial Tobacco Group Limited
4,715,389 12/29/87	Lowers ratio of particulate matter to nicotine in smoke using internal heat sinks and special nicotine-containing adsorbent.	R.J. Reynolds Tobacco Company
4,595,024 6/17/86	Segmented cigarette that delivers a larger amount of nicotine in the first few puffs of the cigarette than in the last few puffs.	R.J. Reynolds Tobacco Company

Development of New Nicotine-Like Molecules

Patent No. Date	Description	Assignee
5,138,062 8/11/92	Nicotine analogs with tranquilizing effects.	Phillip Morris Incorporated
5,015,741 5/14/91	Nicotine analogs exhibiting tranquilizing effects in mammals.	Phillip Morris Incorporated
4,590,278 5/20/86	Preparation of cotinine and nicotine analogs.	Phillip Morris Incorporated
4,155,909 5/22/79	Improved manufacture of 2-alkylnicotinoids.	Phillip Morris Incorporated
4,321,387 3/23/82	Preparation of nicotine analogs, particularly, enantiomerically pure nicotine analogs containing alkyl substituents on the pyridine ring at 4, 5, and/or 6 positions.	Phillip Morris Incorporated
4,220,781 9/02/80	Improved methods for producing 2-alkyl nicotinoles.	Phillip Morris Incorporated
4,442,292 4/10/84	Preparations of cotinine and nicotine analogs.	Phillip Morris Incorporated
4,452,984 6/05/84	Preparations of cotinine and nicotine analogs.	Phillip Morris Incorporated
4,332,945 6/01/82	Preparations of cotinine and nicotine analogs.	Phillip Morris Incorporated

Sales-Weighted Nicotine and Tar Levels in Smoke As % of 1982 Levels Average of All Brands*



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British American Tobacco Memo: 28 Aug 1979

T. Lewan. *Tab Control* 1998; 7:315-319 (Autumn)

- "We are searching explicitly for a socially acceptable addictive product involving: a pattern of repeated consumption; a product which is likely to involve repeated handling; the essential constituent is most likely to be nicotine or a 'direct' substitute for it."

Major Medical Organization Concluding Nicotine is Addictive

- ◇ U.S. Surgeon General
- ◇ World Health Organization
- ◇ American Medical Association
- ◇ American Psychiatric Association
- ◇ American Psychological Association
- ◇ The Royal Society of Medicine
- ◇ Medical Research Council, U.K.

FDA Advertising Proposal:

- Ban Cartoon Graphics and Colorful Graphics
- Text Only Allowed
- Ban Brand Names on Hats, Tee shirts & Other Products
- Event Sponsorship: Require Corporate Name Not Product Name
- Eliminate Vending Machines, Free Samples, Mail Order
 - 22% of 13 Yr Olds & 2% of 17 Yr Olds Buy From VM's
- Eliminate Self Service in Stores
- Suspend Licenses to Those Who Sell to Minors

History of FDA Rule:

August 23, 1996

President Clinton announces the U.S. Food and Drug Administration's (FDA) of tobacco product regulations, known as the FDA Rule.

October 15, 1996

Tobacco industry files lawsuit against FDA Rule:

1. FDA has no authority over tobacco products under FDCA
2. Tobacco products are neither drugs nor drug delivery devices
3. FDA Rule's marketing restrictions violate the First Amendment

Plaintiffs

- COYNE BEAHM, INC
- UNITED STATES TOBACCO COMPANY, et al.
- NATIONAL ASSOCIATION OF CONVENIENCE STORES, et al.

Sideshow: McCain Bill

November 7, 1997

McCain introduces Universal Tobacco Settlement Act.

April 1, 1998

Senate Committee on Commerce passes a revised McCain Bill that includes many of the elements of the FDA Rule.

June 17, 1998:

McCain Bill is defeated in the U.S. Senate.

U.S. Court of Appeals

- August 14, 1999: Fourth Circuit judicial panel votes 2 to 1 that the FDA has no statutory authority to regulate tobacco products
- Because it rules that FDA has no authority, the 4th Circuit does not rule on whether the FDA rule's marketing restrictions violate the 1st Amendment.

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Federal Court System

- 94 Federal District Courts
- 12 Regional Appellate Courts
- 1 Supreme Court:
 - 1 chief justice
 - 8 associate justices

Master Settlement Agreement with the Tobacco Industry and Cigarette Advertising in Magazines

- In 1998, the attorneys general of 46 states signed a Master Settlement Agreement with the four largest tobacco companies in the United States.
- The agreement prohibits tobacco advertising that targets people younger than 18 years of age.

Master Settlement Agreement with the Tobacco Industry

- Tobacco companies cannot use cartoon characters, such as “Joe Camel,” to advertise their products.
- Tobacco companies cannot target youth in the advertising, promotion or marketing of tobacco products.
- Tobacco companies cannot sponsor concerts or other events with significant youth audiences, including team sporting events, such as football games.
- Tobacco brand names cannot be advertised at stadiums and arenas. Source: www.firstamendmentcenter.org/speech.

Americans with Disabilities Act (ADA)

- The Americans with Disabilities Act (ADA) may authorize limiting or eliminating ETS in the workplace.
- The ADA requires that an employer make a reasonable accommodation to the known disabilities of an employee who requests such an accommodation.
- Individuals who suffer from respiratory conditions or illnesses that limit their ability to breathe may request an accommodation that would reduce ETS exposure in the workplace.

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***Another Settlement:
Airline Flight Attendants Lawsuit***

60,000 flight attendants, who never smoked, sued the major U.S. cigarette manufacturers in the Florida Circuit Court in Miami.

Case settled when the four cigarette manufacturers agreed to pay \$300 million to fund scientific research into smoking-related diseases.

*FOOD AND DRUG ADMINISTRATION et al. v. BROWN
& WILLIAMSON TOBACCO CORP. et al.*

Sup. Ct. Ruling March 1, 2000, 5-4 Decision

***Existing law does not provide FDA
authority over tobacco or tobacco marketing.***

***Supreme Court....FDA v Brown and
Williamson Continued...***

FDA consistently stated before 1995 that it lacked jurisdiction over tobacco.

And that Congress has enacted several tobacco-specific statutes fully cognizant of the FDA's position...

Congress...considered and rejected many bills that would have given the agency such authority.

Is is a Drug?

"In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products uniquely contain and deliver nicotine, a potent drug with a variety of physiological effects."

Claude E. Teague, Jr.
R.J. Reynolds executive



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Decision Hinged on FDCA Definition of Drug:

If it's a Drug, then Where's the Benefit?

"Various provisions in the Act require the agency to determine that, at least for some consumers, the product's therapeutic benefits outweigh the risks of illness or serious injury."

"This the FDA cannot do, because tobacco products are unsafe for obtaining any therapeutic benefit."

The inescapable conclusion is that there is no room for tobacco products within the FDCA's regulatory scheme.

If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit."

Justice Sandra Day O'Connor on FDA Authority

"The agency has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States."

Yet...

"We believe that Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products,"

Supreme Court Majority Opinion

"Congress has foreclosed a ban of such products, choosing instead to create a distinct regulatory scheme focusing on the labeling and advertising of cigarettes and smokeless tobacco."

"Its express policy is to protect commerce and the national economy while informing consumers about any adverse health effects."

Justice Stephen Breyer's Dissent on FDA Authority...

"According to the FDA, only 2.5% of smokers successfully stop smoking each year, even though 70% say they want to quit and 34% actually make an attempt to do so."

"The fact that only a handful of those who try to quit smoking actually succeed illustrates a certain reality—the reality that the nicotine in cigarettes creates a powerful physiological addiction flowing from chemically induced changes in the brain."

Breyer, Continued...

“The FDA has found that the makers of cigarettes “intend” these physical effects.

Hence, nicotine is a “drug”; the cigarette that delivers nicotine to the body is a “device”; and the FDCA’s language, read in light of its basic purpose, permits the FDA to assert the disease-preventing jurisdiction that the agency now claims.”

Family Smoking Prevention and Tobacco Control Act June 2009

Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to grant the Food and Drug Administration (FDA) authority to regulate the advertising, marketing, and manufacturing of tobacco products.

Reinstates FDA's 1996 Rule

Restricts tobacco marketing and sales to youth

Bans all outdoor tobacco advertising within 1,000 feet of schools

Bans all tobacco-brand sponsorships of sports and entertainment events;

Bans free giveaways of any non-tobacco items with the purchase of a tobacco product;

Limits to black-and-white text only advertising in publications with significant teen readership,

Restricts vending machines and self-service displays to adult-only facilities;

Requires retailers to verify age for all over-the-counter sales

Family Smoking Prevention and Tobacco Control Act

Provides FDA with authority to develop regulations that restrict the advertising and promotion of a tobacco product consistent with, and to the full extent permitted by, the first amendment to the Constitution.

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Requires detailed disclosure of tobacco product ingredients

Tobacco companies would be required to disclose to the FDA the ingredients in each tobacco product, giving the Agency the information needed to begin reducing the harm caused by tobacco products and educating the public about the health effects of tobacco use.

Family Smoking Prevention and Tobacco Control Act

Allows FDA to require changes to tobacco products to protect the public health...

FDA would be granted authority to reduce nicotine, and to ban hazardous ingredients.

BUT, it would not be allowed to require the reduction of nicotine in a tobacco product to zero or to ban a class of tobacco products.

Family Smoking Prevention and Tobacco Control Act

Reduced Harm Products....

Prohibits the use of descriptors, such as "light", "mild", and "low" on labels or in advertising.

Family Smoking Prevention and Tobacco Control Act

Requires larger, more specific health warnings - to cover the top 50% of the front and rear panels of the package.

Directs FDA to issue a rule requiring graphic warning labels on cigarette packages within two years of enactment.

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Family Smoking Prevention and Tobacco Control Act

Cost of FDA Regulation:

All tobacco-product-related FDA costs are allocated among the manufacturers of cigarettes, cigarette tobacco, and smokeless tobacco products sold in the United States, based on the manufacturers' respective shares of the entire U.S. market.

Tobacco Control Programs Work

- California – Adult smoking dropped from 26.7% to 18.1% between 1998 – 1996.
- Massachusetts – Smoking declined 31 percent between 1992 and 1999.
- Oregon – Tobacco use fell 11.3% since 1996.
- Florida – In one year, teen smoking witnessed largest decline in this nation since 1980.

Key Elements of a Successful Tobacco Control Program

- Elements rated most effective
 - Mass media campaigns
 - Smoking bans and restrictions
 - Price increases
 - Selected types of physician interventions

Source: "Recommendations Regarding Interventions to Reduce Tobacco Use and Exposure to Environmental Tobacco Smoke," Am J Prev Med 2001; 20.

Mass Media Works

- In 1967 – Fairness Doctrine campaign resulted in significant declines in smoking.
- California – The media campaign alone reduced sales of cigarettes by 232 million packs, '90 – '92.
- California – When media spending dropped from \$16 million to \$6.6 million, the program overall became less effective.

Forms of Argument:

Do they differ systematically across case histories?

If yes, how and why?

Industry Arguments

1. Emphasize Benefits of Product or Technology and Social Demand
2. Argue that Evidence is Insufficient to Justify Reg: Play the Good Scientist
3. Trivialize Claim of Hazard: Compare it to Natural Hazards
4. Exposure: Average nationally, yearly and demographically
5. Age Restrictions, Labeling, Training, and Licensing are Acceptable
6. Registration Is a Property Right: Prohibition Demands Compensation (5th Amend.)
7. Patent Life: Long Lag Time; Existing Stock Provision
8. Strategically Regulate Rather Than Ban
9. If Product is Banned Domestically: Let Us Export
10. Substitutes: Don't Compare Among Competitors
11. Comparative Risk: Spend \$ on Seat Belts, Drug Control and Suicide Prevention
12. Self Study, Monitoring and Self Reporting Data and Science.

Environmental & Consumer Group Arguments:

1. Shift Burden of Proof to Private Sector: Demonstrate Safety
2. Evidence is Insufficient to Justify Finding Safety (Need 10XSF)
3. Susceptibility: Toxicity: Developmental, Endocrine, Neuro, Immune: Data Are Incomplete...Don't Wait
4. Exposure: Demand Distributional Analysis by Age Class
5. Mixtures: Common Mechanism Demands Collective Analysis
6. Aggregate Exposure: Air, Water, Foods, Indoor/Outdoor, CP's
7. Pace of Review: Keep to Schedule or See you in Court
8. Restricted Use, Label Changes and Ecological Restrictions....
9. Environmental Testing: EWG—25 million exposed
10. Are the most exposed the most susceptible?
11. Oppose Federal Preemption of State and Local Control

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