



CAMPAIGN
for
TOBACCO-FREE
Kids

FDA REGULATION OF TOBACCO:

**A key Addition to the Efforts of the
States Because it complements State
Efforts to Reduce Tobacco Use and
Curtail Tobacco Industry Behavior**

**Matthew Myers
October 16, 2007**



Despite the MSA FDA regulation is needed for States to Accomplish their public health goals

- **The tobacco industry continues marketing that appeals to children and is deceptive in ways that are difficult for states to reach**
- **States are preempted from regulating local marketing**
- **Unsubstantiated health claims are often hard for states to challenge**
- **Low tar product marketing undermines prevention**
- **Tobacco products remain toxic and addictive and the challenges of product regulation have meant that states have not tried**
- **Weak federal health warnings are preemptive and undermine state efforts**



Ending the Tobacco Problem - A Blueprint for the Nation

Institute of Medicine
May 2007

- “The committee concludes that product regulation by the FDA will advance tobacco control efforts in the United States and around the world. The proposed Tobacco Control legislation embodies the principles that should govern the regulation of tobacco products in the coming years.”



President's Cancer Panel's Answer August 2007

- “The Panel recommends foremost that the influence of the tobacco industry – particularly on America’s children – be weakened through strict Federal regulation of tobacco product sales and marketing.”

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SURGEON GENERAL'S WARNING: Quitting Smoking
Now Greatly Reduces Serious Risks to Your Health.

BE BOLD.

KOOL
BE TRUE.

MILDS B&W: 10 mg "tar", 0.9 mg nicotine, FILTER KINGS
B&W: 16 mg "tar", 1.2 mg nicotine, av. per cigarette by
FTC method. Actual amount may vary depending on how
you smoke. For TRN info, visit www.rjtt.com.

GQ, August and
April 2006; *Sports
Illustrated*,
February 17,
2006.

Courtesy of
trinketsandtrash.org

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BACK TO SCHOOL SPECIALS

GAMEL



*Excludes Camel Non Filter
& Kamel Red

\$ 2.69

PER PACK

WHEN YOU BUY 3



Camden, Delaware

2006


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new

CAMEL

No. 9



light & luscious

SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

9 mg. "tar", 0.8 mg. nicotine av. per cigarette by FTC method. Actual amount may vary depending on how you smoke. For T&N info, visit www.rjrttanic.com

*InStyle, Cosmopolitan,
Elle, Marie Claire,
Vogue, January 2007;
Lucky, February 2007.*



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Washington DC, April 2006



Impact of Price Discounts

- **From 1997 to 2002, the average retail pack price of cigarettes increased by nearly 91 percent, and youth smoking rates declined by 26.8 percent among twelfth graders and 44.8 percent among eighth graders.**
- **From 2002 to 2004, the avg retail pack price barely increased at all (only two cents, or .5 percent) despite a 28 percent increase in state cigarette taxes, and youth smoking declines slowed markedly - the decline was only 6.4 percent among twelfth graders and 14 percent among eighth graders.**



*Enjoy these coupons.
You'll find flavor at every turn.*

SPECIAL OFFERS ENCLOSED

\$3.00 OFF
ONE CARTON *of any style*
MARLBORO



MANUFACTURER'S COUPON | EXPIRES 03/31/08

\$3.00 OFF
ONE CARTON *of any style*
MARLBORO



MANUFACTURER'S COUPON | EXPIRES 03/31/08



The Product is Critical

- **Highly engineered and finely tuned Nicotine Delivery Devices**
- **Every aspect controlled by the tobacco companies, with no government oversight or even disclosure**
- **Products designed in ways that appeal to targets, sustain addiction, assuage health concerns, create an image**
- **Design decisions ultimately and exclusively based on tobacco company bottom line – and often undermine public health goals**

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CAMEL

PLEASURE
To
BURN

*The official blends of summer
— for a limited time only —*



KAUAI KOLADA, TWISTA LIME: 11 mg. "tar", 0.9 mg. nicotine, av. per cigarette by FTC method. For more product information, visit www.rjrt.com

**SURGEON GENERAL'S WARNING: Cigarette
Smoke Contains Carbon Monoxide.**

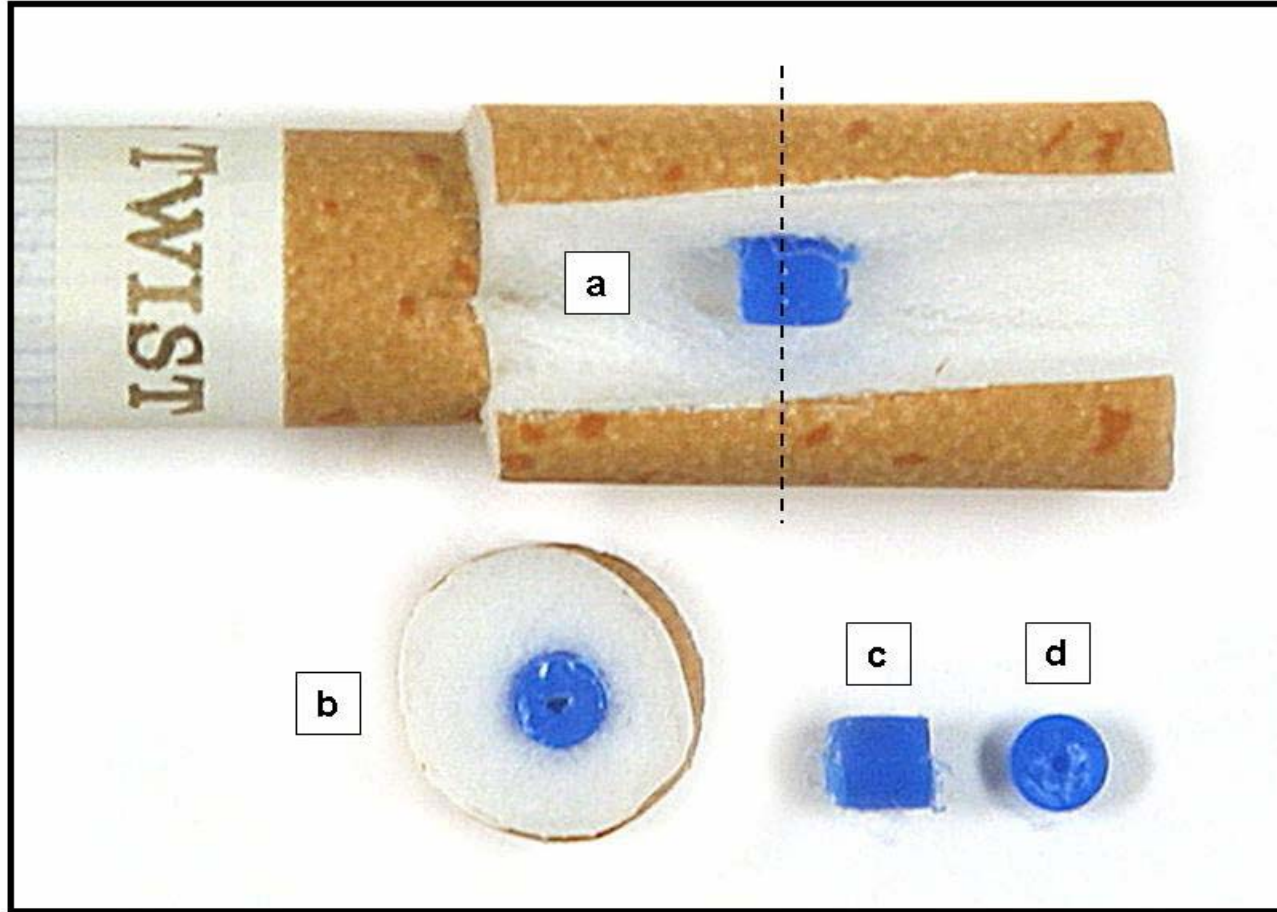
Tin of Cherry Skoal (2007)



A former UST sales representative revealed that, “Cherry Skoal is for somebody who likes the taste of candy, if you know what I’m saying.”

“Juiced Up: How a Tobacco Giant Doctors Snuff Brands to Boost Their ‘Kick,’” *The Wall Street Journal*, 26 October 1994.

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Compounds released from filter pellet of Camel Twist



- α -linalool
- p-menth-1-en-8-ol
- Dodecane
- Decanal
- α -citronellol
- citral
- 1-Decanol
- p-Mentha-1(7),8(10)-dien-9-ol
- Tridecane
- Undecanal
- α -Cubebene
- Limonenediol
- diacetin
- Copaene
- β -elemen
- Tetradecanal
- Dodecanoic acid, 1-methylethyl ester
- Heptadecane
- Nonadecane
- Heptadecane, 2,3-dimethyl-
- Tetradecane
- Caryophyllene
- Dodecanal
- β -Cubebene
- ζ -Elemene
- α -Caryophyllene
- γ -Muurolene
- Valencene
- α -Candinene
- Pentadecane
- β -Candinene
- Hedycaryol
- Caryophyllene oxide
- Hexadecane
- 1,4-Methanobenzocyclodecene, 1,2,3,4,4a,5,8,9,12,12a-decahydro-
- Octadecane
- 3,7,11,15-Tetramethyl-2-hexadecen-1-ol
- Eicosane

*Based on high MS response of peak in chromatogram

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, :
Plaintiff, : Civil Action No. 99-2496 (GK)
and :
TOBACCO-FREE KIDS ACTION FUND, :
AMERICAN CANCER SOCIETY, :
AMERICAN HEART ASSOCIATION, :
AMERICAN LUNG ASSOCIATION, :
AMERICANS FOR NONSMOKERS' RIGHTS, :
and NATIONAL AFRICAN AMERICAN :
TOBACCO PREVENTION NETWORK, :
Intervenors, :
v. :
PHILIP MORRIS USA, INC., :
(f/k/a Philip Morris, Inc.), et al., :
Defendants. :

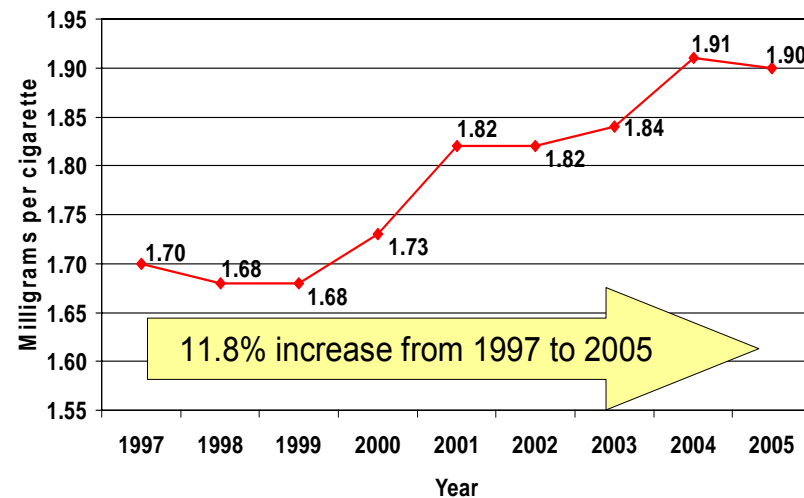
FINAL OPINION

“For Decades, Defendants Have Recognized that Controlling Nicotine Delivery, in Order to Create and Sustain Smokers’ Addiction, Was Necessary to Ensure Commercial Success”

“Defendants Researched, Developed, and Utilized Various Designs and Methods of Nicotine Control to Ensure that All Cigarettes Delivered Doses of Nicotine Adequate to Create and Sustain Addiction”

Increased Nicotine Levels in Cigarettes Average Nicotine Yields Per Cigarette 1997-2005

Harvard School of Public Health, 2006



Excerpts from *U.S. v. Philip Morris USA, Inc., et al.*, (Final Opinion) (August 17, 2006)

RJR document Identified the Specific Characteristics to Be Used in Developing "New Brands Tailored to the Youth Market."



- * Nicotine level of 1.0- 1.3 mg/cigarette;
- * Nicotine absorption minimized "by holding pH down"
- * Tar content of 12-14 mg/cigarette to achieve desired taste and "visible" smoke

- * Bland smoke to address "low tolerance for smoke irritation" of "beginning smoker[s] and inhaler[s]"
- * Suggests 100 mm "to facilitate lighting"
- * "Reasonably firm" rod

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“Light” cigarettes are still the choice



National Cancer Institute's Monograph
13 Reveals The Low-tar Lie – 2001

- Study found “light” and “low-tar” cigarettes no less harmful than other brands
- Tobacco industry deliberately marketed low-tar cigarettes to prevent smokers from quitting

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

OMNI Kings and 100s: 14 mg "tar," 1.1 mg nicotine; Light Kings: 10 mg "tar," 0.8 mg nicotine; Ultra Light 100s: 8 mg "tar," 0.5 mg nicotine, av. per cigarette by FTC Method.

Reduced carcinogenic content measured to meet a specific target level.

WARNING: Smoking is addictive and dangerous to your health. Reduction in carcinogens (PAHs, nitrosamines, and catechols) has NOT been proven to result in safer cigarettes. This product produces tar, carbon monoxide, and other harmful by-products.

NEW!

Omni

Reduced carcinogens.
Premium taste.™

Introducing the first premium cigarette created to significantly reduce carcinogenic PAHs, nitrosamines, and catechols, which are the major causes of lung cancer in smokers.

Introducing the first cigarette to significantly reduce carcinogenic PAH's, nitrosamines, and catechols, which are major causes of lung cancer in smokers.



www.omnicigs.com

孩子眼中的世界——一切都高高在上，他们更需要被平等的注视。
请在与他们交流时，放低你的身姿。

低一点，更多关爱！



低危害卷烟给您更多关爱！

中南海始终致力于卷烟低危害技术和产品的研究与开发。每一款产品都凝结了世界领先的低危害卷烟生产技术，为您的吸烟生活提供健康保证。

卷烟，享受与危害的矛盾体。



A little lower means more loving care! Low-harm cigarettes give you more loving care!

Cigarettes contain conflicting elements of pleasure and harm. Zhongnanhai has always focused on research and development of low-harm cigarette technology. Every product fuses the world's most advanced low-harm cigarette technology, **offering a guarantee of health for your smoking life.**

(Advertisement for Zhongnanhai Lights Cigarettes published in the September, 2006 issue of the company's monthly magazine Zhongnanhai World.)



Impact of the Pending Legislation

- S.625 and HR 1108 provide solutions to each of these problems without curtailing the actions the states have used to reduce tobacco use
- S625 and HR 1108 increase the authority of the states to regulate the time, place and manner of tobacco marketing
- By curtailing tobacco marketing, regulating the manufacture of tobacco products FDA will enhance the efforts of the states



Marketing Regulations

- **Puts in place the marketing restrictions in the 1996 FDA Rule**
- **Gives the FDA ongoing authority and flexibility to regulate tobacco marketing**
- **And – removes FCLA preemption of state marketing restrictions, allowing states to regulate the time, place, and manner of tobacco marketing**
- **States retain authority to regulate sale, distribution, etc. regardless of age**



Key Elements of FDA Rule

- : No outdoor tobacco advertising within 1,000 feet of schools and playgrounds
- No tobacco brand sponsorships of sports and entertainment events
- No free giveaways of any non-tobacco items with the purchase of a tobacco product or in exchange for coupons or proof of purchase
- No free samples and the sale of cigarettes in packages that contain fewer than 20 cigarettes
- Limits point-of-sale tobacco advertising to black-and-white text only
- Limit advertising in publications with significant teen readership to black-and-white text only
- Require retailers to verify age for over-the-counter sales and provide for federal penalties against retailers who sell to minors and funds states to play primary inspection role.

SEC. 906(d) (1)

- The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health.
- *The Secretary* may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to full extent permitted by the first amendment to the Constitution.



Meaningful Warning Labels

- **Authority moved from Congress Over Warning labels**
- **Increased Size and Visibility**
- **Senate version would require graphic warning labels on 50% of front and back of package**
- **House version currently requires strong text labels on 30% of front and back of pack and authorizes FDA to increase them to 50% with graphic labels**
- **Authority of FDA to change text, format and add graphics**



Low Tar/Health Claims

- Bans the terms light and low tar
- Replaces the FTC system for testing and reporting tar and nicotine
- Establishes rigorous standards requiring scientific substantiation before permitting any explicit or implicit health claims and defines such claims broadly



SEC 911

What is Covered ?

Where the Manufacturer represents *explicitly or implicitly that--*

- `(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;*
- `(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or*
- `(III) the tobacco product or its smoke does not contain or is free of a substance;*



SEC 911

The Basic Standard

[T]he Secretary shall approve an application for a modified risk tobacco product filed under this section only if the Secretary determines that the applicant has demonstrated that such product, as it is actually used by consumers, will--

`(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

`(B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.



Authority to set Product Standards

- Authority to require manufacturers to reduce or eliminate substances, including substances determined by FDA to be harmful or to contribute to the harm or addictive impact - whether they are added or occur naturally – where it is technologically feasible to do so
- Use of a Public health standard – not safe and effective
- Focus on both Individual Harm and Population effect
- Authority to remove Substances Without Having to prove That the removal of a Specific Substance will reduce Harm
- Ability to restrict marketing and prohibit claims based on product standards
- Bans characterizing flavorings

SEC. 907

The Secretary may adopt tobacco product standards ... if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health. This finding shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account--

- *‘(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and*
- *‘(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.*



Sec 917 – State/Federal Balance

- *General Rule: No Preemption: Specifically no State Preemption of: any measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products or State, Tribal, or local taxation of tobacco products.*



Sec 917 – State/Federal Balance

What Was preempted?

any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to:

1) tobacco product standards, 2) premarket approval, 3) adulteration, 4) misbranding, 5) labeling, 6) registration, 7) good manufacturing standards, or 9) reduced risk products



Preservation of Right to Sue

Sec 917(b)

No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.



Status

- Approved by Senate HELP Committee
- 55 Senate Sponsors – Awaiting Floor Action
- House Hearing Held; Awaiting Mark-Up in Subcommittee and Committee – a majority of both are sponsors, including the Chairmen of both the Subcommittee and Full Committee
- Over 200 House Sponsors
- Supported by Democratic leadership in both Houses
- Boosted by IOM and President's Cancer Panel – Supported by former FDA Commissioner Kessler; Not supported by current FDA Commissioner