National Cancer Institute

Proposed FDA Authority to Regulate Tobacco

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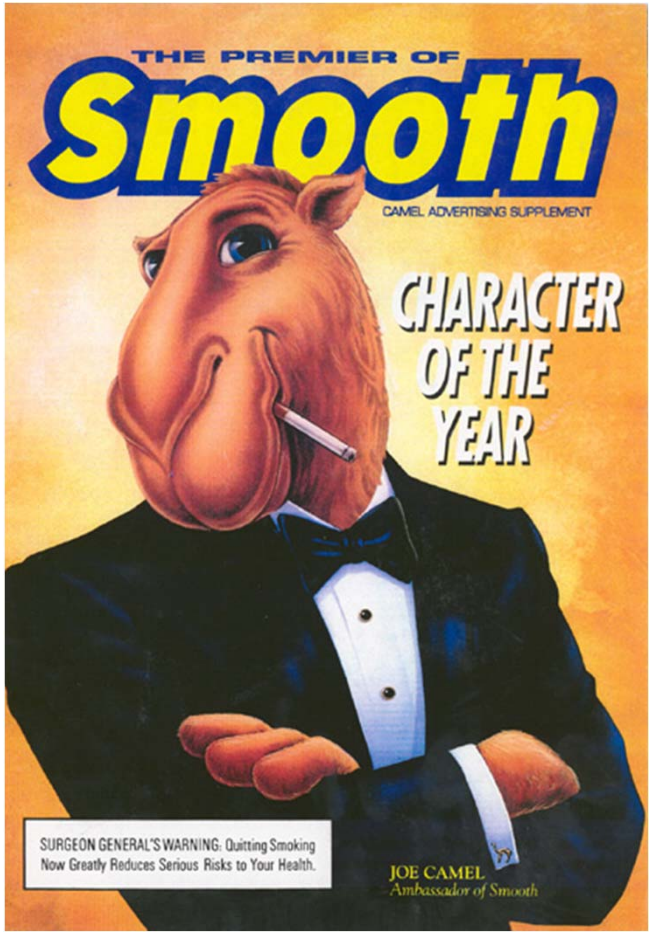
Family Smoking Prevention and Tobacco Control Act (S. 625/ H.R. 1108)

- Currently, FDA does not have authority to regulate tobacco products, the leading cause of cancer deaths
- February 15, 2007 - FDA legislation introduced in U.S. House and Senate
  - Senate sponsors: Senators Edward Kennedy (D-MA) and John Cornyn (R-TX)
  - House sponsors: Representatives Henry Waxman (D-CA) and Tom Davis (R-VA)

Reinstates FDA Rule on Youth Tobacco Use

- Reinstates the 1996 FDA Final Rule restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents

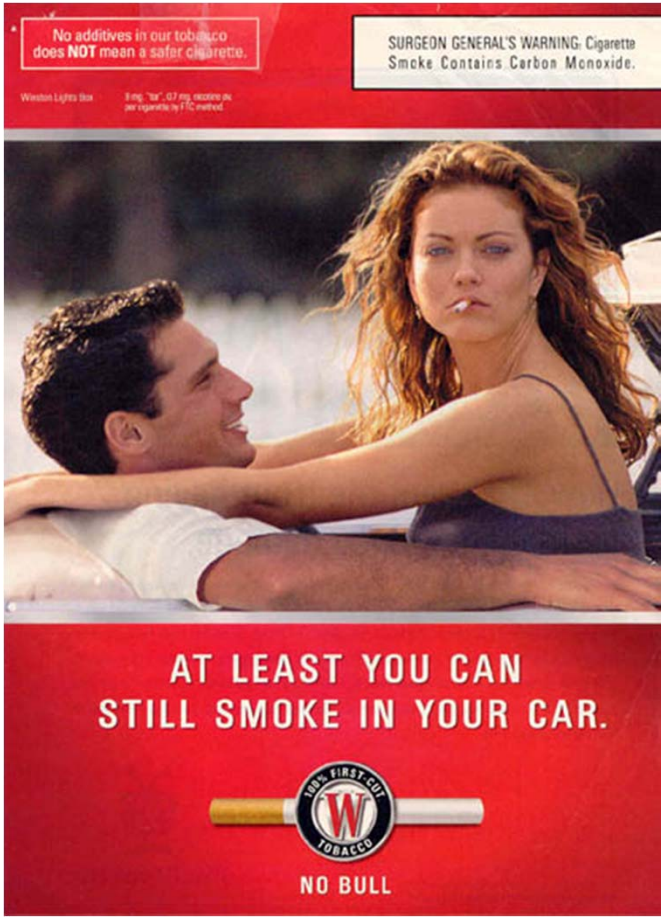
- Science base
  - Overwhelmingly, tobacco use (both cigarettes and smokeless) is initiated by children and adolescents
  - Measures that limit access and appeal can be expected to decrease youth's tobacco use



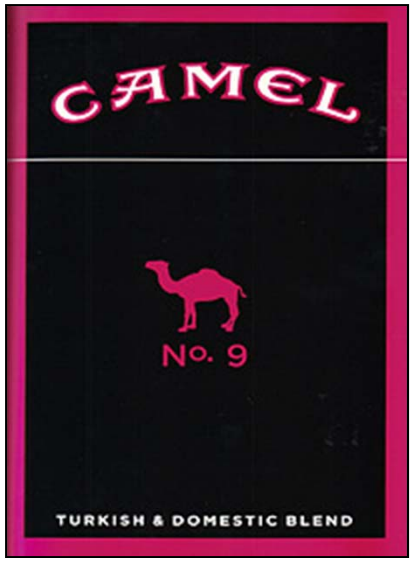
Restricts Tobacco Marketing

- Authorizes FDA to restrict tobacco marketing when appropriate for the protection of public health, consistent with first amendment

- Science base
  - Cigarettes are heavily marketed: >$13 billion, 2005
  - Cigarette advertising increases young people's risk for smoking
  - Marketing of filtered and low-yield cigarette brands is deceptive



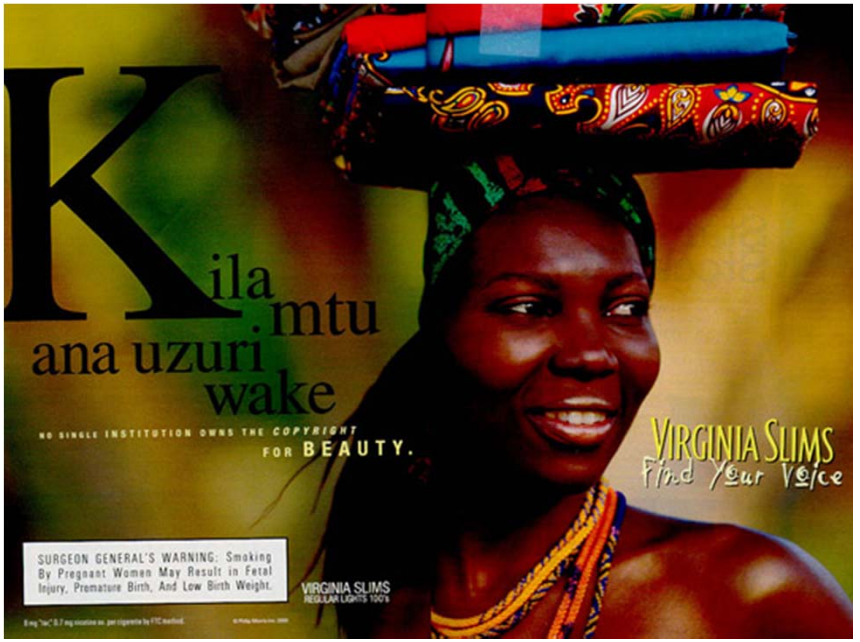
Example: Marketing of “Camel No. 9”



Giveaways & Promotions

Requires Extensive Information Disclosure

- Requires extensive disclosure for ingredients, nicotine, design features, health, toxicology, etc.



- Science base
  - Currently, public has little knowledge and no control over tobacco product ingredients or design features
  - Valuable new information for the scientific community

Bans Cigarette Flavorings

- Bans all cigarette flavorings, other than tobacco or menthol, that are “characterizing flavors” of the product

- Science base
  - Manufacturers add flavorings to enhance their appeal to specific target groups, such as women or young people
  - Banning characterizing flavorings may decrease these products’ appeal, benefiting public health

Tobacco “Product Standards”

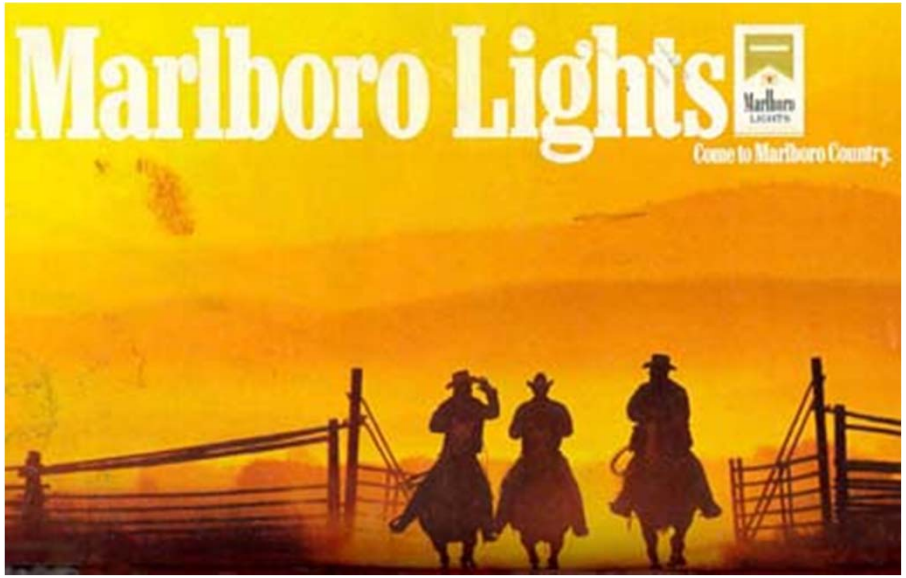
- Grants FDA the authority to establish and periodically re-evaluate tobacco “product standards”

- Science base
  - Wide variation in levels of carcinogens and other constituents
  - Some ingredients and design features are known to make the cigarette product more dangerous

Bans Terms: “Light,” “Low,” and “Mild”

- Bans descriptors that imply that some cigarettes are less hazardous

- Science base
  - NCI Monograph “Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine”



Regulates "Modified Risk" Products and Their Accompanying Health Claims

- FDA granted authority to regulate "modified risk" products - "those sold or distributed for use to reduce harm or risk of tobacco-related disease" - considering the impact on both the individual and the population

- Science base
  - Tobacco companies are already marketing "modified risk" products and making health claims for them, without any oversight
  - FDA authority would bring science to bear on understanding and regulating "modified risk" products

Strengthens Tobacco Product Warning Labels

- Grant FDA authority to revise cigarette package warning labels

- Science base
  - Tobacco product warning labels are an effective way to directly reach tobacco users
  - Effectiveness of the warning increases with size
  - Labels that incorporate pictures are more effective than text-only warnings

Other Provisions

- Establishes Tobacco Products Scientific Advisory Committee
- User fees paid by manufacturers
- FDA may “fast-track” research and approval of cessation products

Some Questions Raised by Legislation

- Will FDA regulation harm public health by misleading consumers to believe tobacco products are “endorsed” by FDA?
- How will FDA regulate new and “modified risk” products in the absence of a complete science base?
  - IOM Report “Clearing the Smoke,” and other reports provide a possible framework for evaluating “modified risk” tobacco products
  - Legislation provides the flexibility for regulation to evolve as scientific knowledge and expertise increases

New IOM Report on Tobacco Control

- *Ending the Tobacco Problem: A Blueprint for the Nation*. (May 2007)
  - FDA should have "have broad regulatory authority over the manufacture, distribution, marketing and use of tobacco products."

- Many smokers think FDA already regulates tobacco*
  - 43.6% of smokers think "cigarettes are evaluated for safety by the U.S. FDA before they are sold to consumers"
  - 78.8% of smokers think FDA should be required to evaluate cigarettes

*Beliefs About Nicotine Delivery Survey, Roswell Park Cancer Center

NCI and NIDA Funding Initiative

- Program Announcement: PA-07-174 (R01) and PA-06-361 (R21)
  - "Testing Tobacco Products Promoted to Reduce Harm"
    - http://grants.nih.gov/grants/guide/pa-files/PA-07-174.html
    - http://grants.nih.gov/grants/guide/pa-files/PA-06-361.html
    - (*)The applications accepted through May and March 2009, respectively
- Key research question
  - "Do potential reduced-exposure tobacco products (PREPs) provide a truly, less-harmful alternative to conventional tobacco products, both on the individual and population level?"

Currently Funded Grants

Safety of Nicotine Reduction Strategy
Dr. Neal Benowitz, UCSF

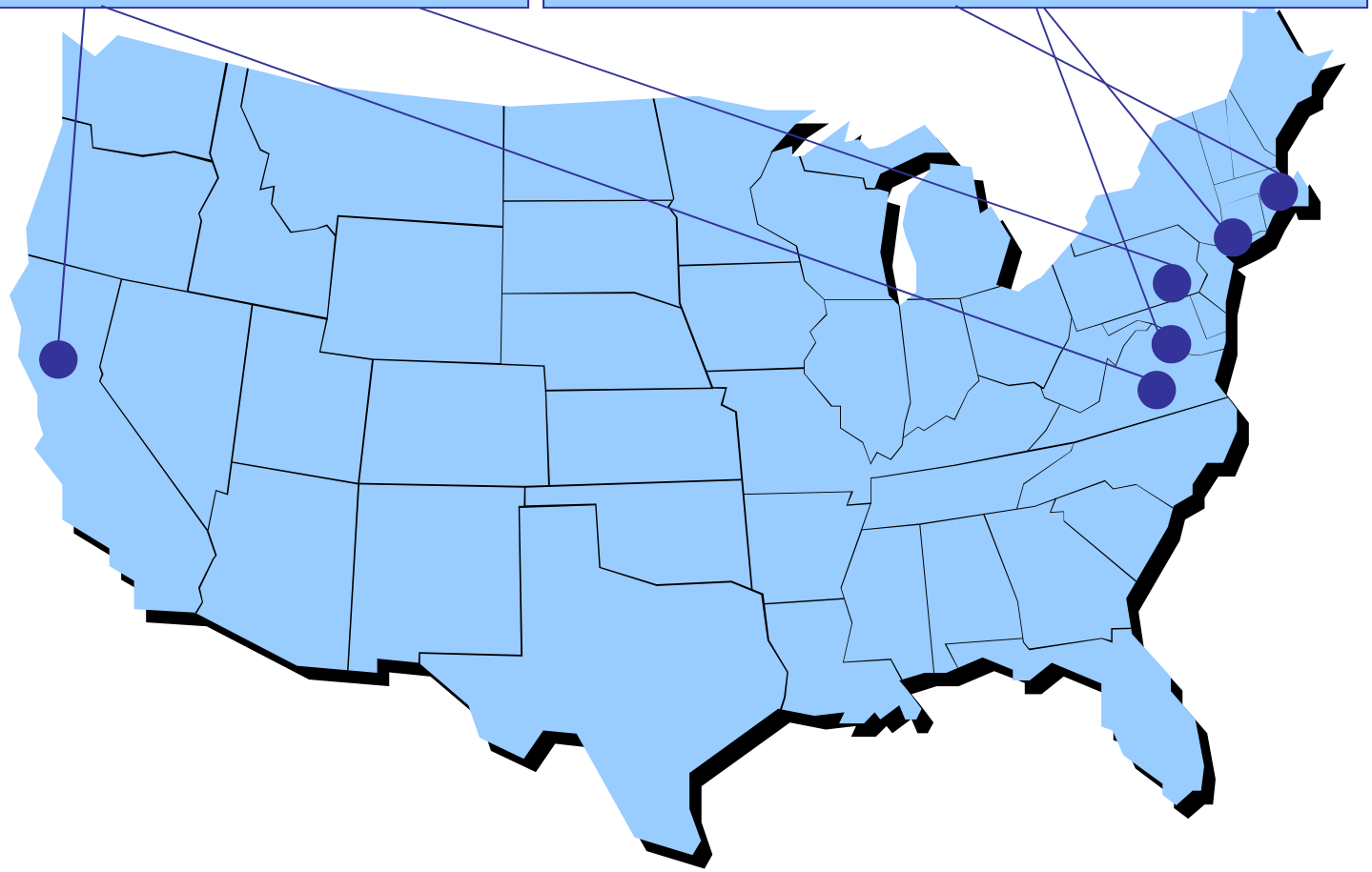
Laboratory Based Evaluation of Tobacco Harm Reduction
Dr. Jerry Rice, Georgetown University

Smoking Topography and Harm Exposure in a New PREP
Dr. Andrew Strasser, University of Pennsylvania

Mutagenicity of Tobacco Smoke in Human Cell Co-culture
Dr. Joseph Gutenplan, New York University

Clinical Models for Evaluating PREPs for Tobacco Users Dr.
Thomas Eissenberg, Virginia Commonwealth University

Evaluating Low-Ignition Propensity Cigarette Legislation
Dr. Richard O'Connor, Roswell Park Cancer Institute



NCI Research and Development Contract

- R&D Contract: "Laboratory Assessment of Tobacco Use Behavior and Exposure to Toxins among Users of New Tobacco Products Promoted to Reduce Harm"

Awarded to:	Georgetown University
P.I.:	Peter Shields, M.D.
Time frame:	September 2006 to September 2011
Annual cost:	~ $ 3 million/year (Years 1-5)
Potential investment:	$ 17 million

  - Collaborating study sites
    - University of Minnesota (Drs. Dorothy Hatsukami and Steve Hecht)
    - Roswell Park Cancer Institute (Dr. Michael Cummings)
    - Harvard University, School of Public Health (Dr. Gregory Connolly)
    - Arista Laboratories (Dr. Richard Higby)

R&D Contract Objectives

- Assess how differences in individual smoking behaviors influence exposure and uptake of addictive, toxic, and carcinogenic agents among users of new and modified tobacco products
- Review, develop, and validate laboratory methods for assessing exposure and risk (e.g., smoking topography, biomarkers, *in vitro* testing) from tobacco products
- Create a public database of laboratory and clinical research methods and protocols for studying new and modified tobacco products

Important Research Questions

- How do changes in ingredients and product design impact
  - tobacco use behaviors?
  - emissions of nicotine and toxic chemicals?
- What methods and measures can be used to assess the impact of changes in ingredients and product design on
  - actual human exposure to nicotine and toxic chemicals?
  - addictive potential? disease risk?

Nicotine Modification: Strasser et al. 2007

Tested *Quest* cigarettes – 3 levels of nicotine

ELSEVIER

Available online at www.sciencedirect.com
ScienceDirect

Drug and Alcohol Dependence 86 (2007) 294–300

DRUG and ALCOHOL DEPENDENCE
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Short communication

New lower nicotine cigarettes can produce compensatory smoking and increased carbon monoxide exposure

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Important Research Questions (cont.)

- How will the introduction and marketing of “reduced risk” tobacco products change consumers’ perceptions of risk and tobacco use behavior?
- What is the effect of new tobacco products and marketing on population-level patterns of tobacco use, including initiation and cessation?
- What changes in tobacco product warning labels will have the greatest impact on consumers?

Conclusions

- Many challenges and opportunities surrounding FDA implementation
- Proposed legislation provides flexibility for regulations to evolve as scientific knowledge and experience increases
- NCI-supported research has made a critical contribution to the underlying science
- Increased urgency of research questions if proposed legislation is enacted