

# CAMPAIGN For TOBACCO-FREE Kids®

## WHY THE FDA SHOULD REGULATE TOBACCO PRODUCTS

### *WHAT IF ...*

... a product consumed by nearly 50 million Americans every day killed one-third of those who became regular users and one-half of those who use it for a lifetime?

... nearly 90 percent of those using the product for the first time tried it and became regular users when they were 18 years of age or younger?

... the product was not only deadly but also as addictive as cocaine or heroin?

... the manufacturers of the product knew of its harmful and addictive properties and lied to the American public and to the United States Congress about what it knew?

... the manufacturers knowingly developed more addictive versions of their products?

... the manufacturers spent billions of dollars every year to market the product, particularly to children?

Would there be outrage among the public? The declaration of a public health crisis? Calls for product regulation and restrictions and to make it as safe as possible? In the case of tobacco, the answer is there is no special regulation, only special protection.

### *THE DEADLY FACTS ABOUT TOBACCO*

Tobacco is the only legal product sold in the United States that, when used according to the manufacturer's instructions, is highly addictive and kills a high percentage of its regular users.

Tobacco causes nearly one out of every three deaths from cancer, one out of every five deaths from heart disease, and 87 percent of all lung cancer cases.<sup>1</sup>

Every day approximately 3,000 children become regular smokers. One-third of them will die of a tobacco-related illness.<sup>2</sup>

In the 2 ½ years since Congress' last attempt to pass legislation granting authority to the U.S. Food and Drug Administration (FDA) to regulate tobacco,<sup>3</sup> about 2.7 million children have become regular smokers, of whom about 900,000 will die prematurely of tobacco-related illnesses.<sup>4</sup>

Tobacco kills more than 400,000 people each year in the United States. More than AIDS, car accidents, alcohol, homicides, illegal drugs, suicides, and fires ... combined. That's one out of every five deaths.<sup>5</sup>

In the same 2 ½ years since Congress tried giving FDA the authority to regulate tobacco products, *more than one million Americans have died prematurely from tobacco-related illnesses*. That's the equivalent of the combined populations of Jackson, Mississippi, Casper, Wyoming, Abilene, Texas, Billings, Montana, Burlington, Vermont, and Dubuque, Iowa all dying of a tobacco-related illness.<sup>6</sup>

Every year the Federal government spends an estimated \$38 billion on services attributable to tobacco-related illnesses (Medicare, Medicaid, Veterans, etc...).<sup>7</sup> In addition, States spend an estimated \$7.3 billion every year on Medicaid services for tobacco-related illnesses.<sup>8</sup>

Evidence strongly suggests that if individuals do not begin smoking before age 19 they will never start.<sup>9</sup> The tobacco industry spends billions of dollars on marketing every year (more than \$8.2 billion a year – almost \$22.5 million a day<sup>10</sup>), much of which appeals directly to the 18 and under population.

Industry marketing practices create a situation in which smoking by children and adolescents is not a matter of informed choice. Then, once a choice to start smoking is made, many children quickly become addicted to nicotine,<sup>11</sup> making quitting very difficult.

## ***AN ANSWER***

While tragic and mind numbing in its enormity, the death and disease caused by the use of tobacco products is preventable. And while there are no magic bullets in the fight against tobacco, a critical element in this fight is the effective regulation of the sales, marketing and manufacturing of tobacco products.

The U.S. Food and Drug Administration regulates food, drugs and medical devices that range from macaroni and cheese to nicotine gum, to break-through prescription drugs to artificial heart valves ... **but not tobacco products**. Other products manufactured by tobacco companies (e.g., Kraft Macaroni and Cheese, Miller Lite beer), and every other product containing nicotine (e.g., Nicorette, Nicoderm), are regulated by the FDA ... **but not tobacco products**.

The FDA is clearly the most appropriate agency to regulate tobacco products. They have the scientific knowledge and expertise, they are unbiased and objective, and they have years of experience in effectively regulating consumer products.

Any bill that grants the FDA authority to regulate tobacco products must address the following critical set of elements:

**Marketing and Youth Access .** Legislation should grant FDA authority regarding the sale and distribution of tobacco products, including access, advertising, and promotion with a particular emphasis on marketing that appeals to young people and claims that are deceptive or misleading.

**Adoption of Youth Access and Marketing Restrictions of the 1996 Rule to Help Reduce Youth Tobacco Use.** Legislation should incorporate the substance of the youth access and youth marketing restrictions adopted by the FDA in 1996 so that the agency would not need to go through a new rulemaking process to implement them.

**Health Information Disclosure.** Legislation should entitle FDA to receive all documents and information in the tobacco industry's possession relating to health effects of all tobacco products, nicotine and its effects on the body, addiction, marketing to children and its effects, and such other information that the HHS Secretary deems necessary to enable the FDA to protect the public health.

**“Public Health” Standard.** The existing FDA standard for approving drugs and devices is whether there is a “reasonable assurance that a product is safe and effective.” Because there is no such thing as a safe cigarette, this proper standard for regulation of tobacco products should be the “protection of the public health” standard. This standard will give FDA the flexibility to reduce health risks to the American public, taking into account all relevant considerations. This standard would require consideration of whether a product change or new rule will reduce or increase tobacco use, including increasing the number of new users or decreasing the number who quit.

**Authority to Reduce or Eliminate Harmful Components.** Legislation should grant FDA the authority to evaluate scientifically, and then through notice and comment rulemaking to decide whether to reduce or, where appropriate, eliminate the harmful and addictive components of all tobacco products based upon what will best protect the public health.

**Disclosure of Ingredients.** Legislation should grant FDA authority to require the tobacco industry to provide a complete list of all tobacco ingredients and additives, by brand and by quantity, and the authority to require that this information be given to the public in a manner that does not disclose legitimate trade secrets. It should further provide FDA with authority to regulate the use of any ingredient or additive that is harmful or which contributes to the harmfulness of the product. Also, the burden should be placed on tobacco manufacturers to demonstrate that each ingredient and additive is safe in the quantity used under the conditions of intended use.

**Health Warnings.** Legislation should grant FDA authority over health warnings on tobacco product packages and advertisements, including the power to revise and add health warnings and to alter their format, including, but not limited to changing their size, location, and color.

**Health Claims and “Reduced Risk” Products.** Legislation should grant FDA authority over products that purport to reduce consumer health risks or serve as less harmful alternatives and the authority to evaluate scientifically whether new products are actually “less harmful.” It also should provide FDA authority to prohibit or restrict directly or indirectly made: (1) unsubstantiated or false or misleading health claims; and (2) claims that discourage people from quitting or encourage them to start using tobacco.

**FDA Authority over Tobacco Farms or Tobacco Growers.** Legislation should make clear that FDA would not have authority over tobacco farms or tobacco growing.

**Routine Regulatory and Procedural Fairness.** Legislation should subject tobacco products to the same standards or procedures that are applied to other FDA-regulated “drugs” or “devices.”

### ***THE WRONG ANSWER***

Some tobacco companies claim that they now support federal regulation of tobacco, including health claims.

The tobacco industry’s version of regulation is fundamentally different from that supported by the public health community and is aimed at protecting the industry’s profits, not the public health. It would not provide meaningful authority over tobacco marketing or the harm caused by the product itself.

The public health community’s goal is effective regulation that would reduce the number of people who become addicted to and then are sickened and killed by tobacco.

The tobacco industry views “regulation” as a marketing tool (an FDA seal of approval) to promote its new “reduced risk” products that include unproven and unsubstantiated health claims.<sup>12</sup>

If the tobacco industry succeeds in its efforts to pass weak FDA regulation, the result will be fewer smokers attempting to quit and more people starting to smoke – good news for the tobacco industry, bad news for public health.

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<sup>1</sup> US Department of Health and Human Services. Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General. US Department of Health and Human services, Public Health Service Centers for Disease Control and Prevention, Centers for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. DHHS Publication No. (CDC) 89-8411, 1989.

<sup>2</sup> Targeting Tobacco Use: The Nation’s Leading Cause of Death, <http://www.cdc.gov/tobacco/overview/oshaag.htm>.

<sup>3</sup> On June 17, 1998 the Senate defeated the Universal Tobacco Settlement Act (S. 1415), a.k.a., the “McCain” bill.

<sup>4</sup> Targeting Tobacco Use: The Nation’s Leading Cause of Death, <http://www.cdc.gov/tobacco/overview/oshaag.htm>.

<sup>5</sup> Lynch, B.S., and R.J. Bonnie, editors, Growing Up Tobacco Free – Preventing Nicotine Addiction In Children and Youths, Committee on Preventing Nicotine Addiction in Children and Youths, Division of

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Biobehavioral Sciences and Mental Disorders, Institute of Medicine, National Academy of Sciences, Washington, D.C., p.3, 1994.

<sup>6</sup> Based on 1999 U.S. Census Bureau population estimates for metropolitan statistical areas, <http://www.census.gov/population/estimates/metro-city/ma99-02.txt>.

<sup>7</sup> Xiulan Zhang et al, "Cost of Smoking to the Medicare Program, 1993," Health Care Financing Review 20(4); L. Miller et al, "State Estimates of Total Medical Expenditures Attributable to Cigarette Smoking, 1993" Public Health Reports 113.

<sup>8</sup> Ibid.

<sup>9</sup> Federal Register, Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Final Rule, page 44399, August 28, 1996.

<sup>10</sup> For amounts spent by the cigarette companies on marketing, see Federal Trade Commission's "Cigarette Report For 1999," (2001), [www.ftc.gov](http://www.ftc.gov)

<sup>11</sup> DiFranza, Joseph R et al, "Initial Symptoms of Nicotine Dependence in Adolescents," National Cancer Institute grant CA77067-03.

<sup>12</sup> Report of the Institute of Medicine, "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction," National Academy of Sciences, February 22, 2001.