

(Res. 04-01)

## STATEMENT OF POLICY

### SUPPORT OF STRONG FDA REGULATION OF TOBACCO AND NICOTINE PRODUCTS

#### Policy

The National Association of County and City Health Officials (NACCHO) supports strong Food and Drug Administration (FDA) regulation of tobacco. The FDA is a consumer protection agency whose mission is “to promote and protect the public health by helping safe and effective products reach the market in a timely way; to monitor products for continued safety after they are in use, and; to help the public get the accurate, science-based information needed to improve health.”<sup>1</sup> Legislation granting FDA authority to regulate tobacco products should include the following:

- **Youth Access and Marketing.** Granting FDA authority regarding the sale and distribution of tobacco products, including access, advertising, and promotion
- **Adopting the Youth Access and Marketing Restrictions of the 1996 Rule to Help Reduce Youth Tobacco Use.**<sup>2</sup> Legislation should incorporate the substance of the youth access and youth marketing restrictions adopted by the FDA so that the agency would not need to go through a new rulemaking process to implement them.
- **Health Information Disclosure.** Legislation should entitle the 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 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, legislation should create a new “protection of the public health” standard for all tobacco products that refers to reducing health risks to the American public. 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.
- **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.
- **Authority to Reduce or Eliminate Harmful Components.** Legislation should grant FDA the authority to evaluate scientifically, and then through a rulemaking process to reduce or, where appropriate, eliminate the harmful and addictive components of all tobacco products in order to protect the public health.
- **Reduced Risk Health Claims.** 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.” Such authority should allow FDA to prohibit or restrict directly or indirectly made: (1) unsubstantiated health claims; and (2) health claims that discourage people from quitting or encourage them to start using tobacco.
- **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.<sup>3</sup>

Furthermore, NACCHO views weakened FDA regulation that does not reflect these criteria as counterproductive and detrimental to public health and urges tobacco control advocates at the local, state, and national level to advocate for strong FDA legislation.

### **Justification**

“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.”<sup>4</sup> Approximately 63 percent of persons who tried their first cigarette in 2005 were under age 18.<sup>5</sup> New, unregulated tobacco products and nicotine products are being introduced that may be marketed to the public as reduced risk without scientific evidence.<sup>6</sup> The tobacco manufacturers have researched the health effects of their products and access to this information as well as information on the naturally occurring ingredients and additives in tobacco products can be used to protect public health.<sup>6</sup> FDA regulation, as proposed by public health experts, would help protect children and adults, protect public health, provide more information for consumers, and ensure decisions about tobacco and nicotine products are based on sound science.<sup>6</sup>

### **Record of Action**

*Proposed by Tobacco and Chronic Disease Committee*

*Adopted by NACCHO Board of Directors*

*February 26, 2004*

*Updated June 18, 2007*

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<sup>1</sup> *FDA Overview*. <http://www.fda.gov/oc/opacom/fda101/sld001.html>. USDA. Accessed June 18, 2007.

<sup>2</sup> *Draft Public Health Proposals: Tobacco Farming and Public Health Commission*. [www.fsa.usda.gov/tobcom/RecHealth.htm](http://www.fsa.usda.gov/tobcom/RecHealth.htm). Farm Service Agency, USDA. Feb. 21, 2001.

<sup>3</sup> *Critical Elements of any Legislation to Grant FDA Authority to Regulate Tobacco Products*. Campaign for Tobacco Free Kids, American Cancer Society, American Heart Association, American Lung Association. [www.tobaccofreekids.org/research/factsheets/pdf/0181.pdf](http://www.tobaccofreekids.org/research/factsheets/pdf/0181.pdf). Sept. 12, 2003.

<sup>4</sup> *Why the FDA Should Regulate Tobacco Products*. Campaign for Tobacco Free Kids, American Cancer Society, American Heart Association, American Lung Association. [www.tobaccofreekids.org/research/factsheets/pdf/0187.pdf](http://www.tobaccofreekids.org/research/factsheets/pdf/0187.pdf). Sept. 12, 2003.

<sup>5</sup> *Results from the 2005 National Survey on Drug Use and Health: National Findings*. SAMHSA. <http://www.oas.samhsa.gov/nsduh/2k5nsduh/2k5Results.pdf>.

<sup>6</sup> *What Does FDA Regulation of Tobacco Products Really Mean?* Campaign for Tobacco Free Kids, American Cancer Society, American Heart Association, American Lung Association. [www.tobaccofreekids.org/research/factsheets/pdf/0182.pdf](http://www.tobaccofreekids.org/research/factsheets/pdf/0182.pdf). Sept. 12, 2003.