



September 29, 2009

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2009-N-0294

Dear Sir/Madam:

The American Association for Cancer Research (AACR), with over 29,000 members, is the oldest and largest scientific organization in the world dedicated to the prevention and cure of cancer through research, education, communication, and collaboration. We appreciate the opportunity to provide comments in response to the U.S. Food and Drug Administration's (FDA) notice on the Regulation of Tobacco Products.

As we have known for many years, tobacco use is the leading preventable cause of premature mortality, killing more than 5 million people worldwide every year. Tobacco use has a particularly profound impact on cancer incidence and mortality. Indeed, tobacco use is causally associated with 15 different cancers, including lung, head and neck, stomach, pancreas, and cervical cancers, and alone tobacco accounts for 30% of all cancer deaths. The AACR Task Force on Tobacco and Cancer was convened to foster scientific and policy initiatives to reduce the incidence of disease and mortality due to tobacco use.

Given that tobacco use has been definitively proven to cause cancer, the AACR has a keen interest in strategic priorities that the FDA will pursue under the new regulatory authority over tobacco products granted by the Family Smoking Prevention and Tobacco Control Act (FSPTCA). The AACR appreciates the opportunity to participate in the planning for implementation of the FSPTCA and looks forward to future opportunities to provide comments and information as the rulemaking process progresses. Our recommendations below are based on three fundamental premises: (1) there is no known safe form of tobacco; (2) reduction of the morbidity and mortality from tobacco use to the greatest extent possible should be the FDA's goal; and (3) those with interest in sustaining tobacco use will strive to undermine the intent of the legislation.

Given these premises, the AACR makes the following recommendations regarding implementation of the legislation:

1. Develop and implement a plan to reduce delivered amounts of nicotine or other addicting constituents in tobacco products to levels that do not sustain addiction to these products. In addition, to the extent identified by science, modifications of tobacco product design that are proven to reduce addiction potential should be implemented. Reduction of the addicting agents in tobacco to levels that are not addicting to anyone would stop the progression from experimentation with tobacco products to regular use to addiction.
2. Remove, as rapidly as possible, menthol from tobacco products. Most other flavorings have been removed, and menthol should be as well. Mentholized cigarettes are used by a large majority of African American smokers, and there is evidence that menthol helps to sustain tobacco use, in part by making tobacco smoke more palatable. Elimination of menthol will make quitting tobacco less difficult for those who find menthol reinforcing.
3. In collaboration with the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), develop and implement a national surveillance system to track tobacco products and tobacco use with the goal of using the data to serve as an early warning system to track new tobacco products and populations who use them—much as new communicable diseases are tracked.
4. Require stringent and effective warning labels for tobacco products based on scientific evidence.
5. Require that the regulation and labeling of tobacco products be more stringent than that of tobacco use treatments, including nicotine replacement products (NRT), in proportion to the relative harm of these two classes of products.
6. Implement fast track review and approval of tobacco cessation products, and actively lead an initiative to increase tobacco treatment medication development, taking into account genetic, behavioral, and environmental factors, and medication accessibility that is akin to the initiatives that led to dramatic improvements in HIV/AIDS treatment. Develop a coordinated tobacco control effort between the FDA (e.g., in collaboration with the Center for Drug Evaluation and Research) and other government agencies (e.g., NIH, Agency for Healthcare Research and Quality, and Centers for Medicare and Medicaid Services) and the private sector to address this priority.
7. Require that all tobacco product labels include the national toll free quitline number (1-800-QUITNOW), and provide resources to NIH and CDC to test new forms of treatment and increase the national infrastructures (e.g., quitlines) needed to treat more tobacco addicted Americans.

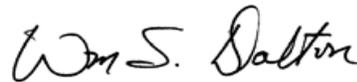
8. In fulfilling obligations under Section 918 of the FSPTCA, act on promoting tobacco cessation to meet the Healthy People 2010 goal to reduce and eliminate health disparities; foster research to understand how tobacco company marketing targets populations; better identify the risk factors for initiation and disease risk among different population groups; develop better methods to promote cessation; and develop better methods to inform the public of the risks of tobacco use.
9. Establish a comprehensive framework for the evaluation of new tobacco products prior to their introduction into the marketplace. We recognize that current research gaps will create early limitations as the FDA implements this framework, and so FDA should fund areas of research gaps that preclude full implementation of the framework.
10. Establish a comprehensive framework for the evaluation of manufacturer's health claims for modified tobacco products, which may overlap with a framework to evaluate all new tobacco products. The evaluation of manufacturer's health claims will need to be assessed by human studies of sufficient size, scope, and duration. Research gaps may currently preclude the substantiation of any manufacturer's claims at this time, and so FDA should fund areas of research gaps that prevent full implementation of the framework.
11. Issue a regulation to deem all tobacco products, including cigars, pipe tobacco, and waterpipe tobacco, subject to the FSPTCA; prohibit these products from having candy, fruit, and spice flavors as characterizing flavors; apply all tobacco package labeling requirements to these products; and apply to these products the youth access and advertising and promotion restrictions of the regulations promulgated in the August 28, 1996, issue of the Federal Register (61 Fed. Reg., 44615-44618).
12. Act to reduce exposure by youth to smoking in media, including motion pictures, through regulatory changes where possible.
13. Support the research of, and issue warnings related to, the toxic effects of tobacco residue in fabrics, upholstery, and air.
14. Ban the sale of gum, candy, or other food products that are designed and packaged to mimic tobacco products. Such products constitute tobacco marketing that appeals to children.
15. Require that the safety and efficacy of any alternative nicotine or tobacco delivery system, including the so-called electronic cigarettes, be established before being marketed or sold in the USA.

The AACR Task Force on Tobacco and Cancer, the full roster of which is enclosed for your information, is willing and able to provide expert information as the FDA implements this critical new law. The AACR stands with the FDA in its efforts to eliminate tobacco use, and its members are prepared to work with the FDA and other partners to make that happen in our lifetime.

Sincerely,



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and Cancer



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Enclosure

The mission of the American Association for Cancer Research is to prevent and cure cancer. Founded in 1907, AACR is the world's oldest and largest professional organization dedicated to advancing cancer research. The membership includes 30,000 basic, translational and clinical researchers; health care professionals; and cancer survivors and advocates in the United States and nearly 90 other countries. The AACR marshals the full spectrum of expertise from the cancer community to accelerate progress in the prevention, diagnosis and treatment of cancer through high-quality scientific and educational programs. It funds innovative, meritorious research grants, research fellowship and career development awards. The AACR Annual Meeting attracts more than 16,000 participants who share the latest discoveries and developments in the field. Special conferences throughout the year present novel data across a wide variety of topics in cancer research, treatment and patient care. The AACR publishes six major peer-reviewed journals: *Cancer Research*; *Clinical Cancer Research*; *Molecular Cancer Therapeutics*; *Molecular Cancer Research*; *Cancer Epidemiology, Biomarkers & Prevention*; and *Cancer Prevention Research*. The AACR also publishes *CR*, a magazine for cancer survivors and their families, patient advocates, physicians and scientists. *CR* provides a forum for sharing essential, evidence-based information and perspectives on progress in cancer research, survivorship and advocacy.



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