



The Consumer Advocates for Smoke-Free Alternatives Association

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December 28, 2009

Lawrence Deyton, MD
Director, Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850-3229

Dear Dr. Deyton:

The Consumer Advocates for Smoke-Free Alternatives Association (CASAA) urges the FDA's Center for Tobacco Products to shift the focus of tobacco control to saving lives. For decades tobacco control laws and smoking cessation treatment efforts have focused on one goal: complete abstinence from nicotine. The Healthy People 2010 smoking prevalence goal was set at 12%. The fact that the number of adult smokers in the US has not decreased, but rather has increased to 46 million (20.6%), leads to an inescapable conclusion: we need a different approach.

If smokers are not quitting, it is not for lack of trying. Millions of smokers find they simply cannot quit smoking, despite multiple attempts and with use of the various FDA-approved cessation products. The success rates for nicotine replacement therapy (NRT) products are abysmal, ranging from 16% to 19% at six weeks, falling to a range of 5% to 10% after therapy stops.

The easy explanation for this phenomenon is "it's an addiction." It's an easy explanation because it allows the medical community, the tobacco control community, and the non-smoking public to simply blame the victim.

However, for a large percentage of long-term smokers, nicotine abstinence triggers cognitive deficits and mood impairments that negatively impact job performance, relationships, and instrumental activities of daily living. The nicotine abstinence approach forces these smokers to pay for improvements in physical health with their cognitive and emotional health. It is unethical to force such a choice on anyone.

The Tobacco Harm Reduction approach saves lives by encouraging smokers to switch to products that provide nicotine from less harmful sources than tobacco smoking. The World Health Organization has observed, "If a tobacco user can only abstain from smoking through the use of a therapeutic dose of 'clean' nicotine, this should be an option. Such products should be made available, and not placed at a marketing disadvantage compared with tobacco products." [1]

One smoke-free alternative, commonly known as the electronic cigarette, delivers vaporized nicotine. In a survey of electronic cigarette users, 79 percent report using them as a

complete replacement for cigarettes, with another 17% of users reducing the number of cigarettes smoked. [2]

CASAA recommends the following actions:

- Encourage switching to reduced harm smoking substitutes such as electronic cigarettes. [3]
- Make it easy to import Swedish snus which has proven to be much safer than smoking. [4]
- Encourage U.S. tobacco makers to emulate the methods used in Sweden to reduce carcinogens in tobacco. [5]
- Encourage the development and marketing of higher dose versions and long-term use of FDA-approved nicotine products as a replacement for smoking. [6]
- Provide accurate safety information on products so that consumers can make informed choices. [7]

The Comprehensive Smokeless Tobacco Health Education Act of 1986 (Public Law 99-252) required a misleading warning label on smokeless tobacco: "This product is not a safe alternative to cigarettes." Smokers who read the label concluded that switching to smokeless was not going to help one bit, so they might as well keep smoking until they were ready to quit. The warning label has resulted in countless cases of lung disease, heart disease, excess cancers, and premature death.

Section 205 of the "Family Smoking Prevention and Tobacco Control Act" authorizes the FDA to revise warning label statements on smokeless tobacco products. A more accurate label would state, "This product reduces disease risk by 95% when used as an alternative to cigarettes."

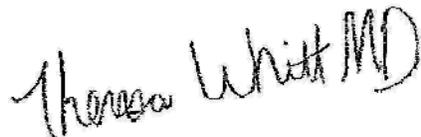
Other smoking alternatives should also carry accurate statements about health effects. Electronic cigarettes users who have stopped smoking tobacco report improvement in lung function and markers of cardiovascular risk. [2, 8]

The FDA has an unprecedented opportunity now to work in the best interest of public health: reduce the death and disability caused by the single most dangerous method of taking in nicotine — tobacco smoking. [9]

Sincerely,



Michal E. Douglas, President



Theresa Whitt, M.D., Medical Director

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