



American Association of Public Health Physicians
The voice of public health physicians, guardians of the public's health
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Tobacco Control Task Force
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Lawrence Deyton, MD
Incoming Director
FDA Center for Tobacco Products

Re: **Don't Write Off Current Smokers**

Dear Dr. Deyton:

For the past half century, the American Association of Public Health Physicians (AAPHP) has served as the national voice of physician directors of state and local health departments and other like-minded physicians. We have long been involved with tobacco control, with the singular goal of doing everything in our power to reduce tobacco related illness and death.

As you assume leadership of the new FDA Center for Tobacco Products, we urge you to consider the actions FDA can take, within the powers granted by this new legislation, to rapidly and substantially reduce tobacco-related illness and death in current adult smokers.

Unfortunately, FDA has not gotten off to a good start. FDA condemnation of electronic cigarettes, in its July 22 press conference, and FDA insistence that electronic cigarettes should be regulated as a drug/device combination rather than as a tobacco product makes no sense from a public health perspective. It flies in the face of FDA laboratory findings on other products already approved by FDA. If one looks at electronic cigarettes as a sentinel for all tobacco products less hazardous than conventional cigarettes – the outlook for FDA action reducing tobacco-related illness and death among current adult smokers is dismal.

With this in mind, we respectfully request your consideration of the following actions:

1. We urge FDA to make public the laboratory data behind the July 22 condemnation of electronic cigarettes, along with comparable data on pharmaceutical nicotine products and conventional cigarettes. Then, on the basis of these data, either fully justify or retract the July 22 condemnation of electronic cigarettes.

2. We urge FDA to reclassify electronic cigarettes from a drug/device combination to a tobacco product. This will enable FDA to immediately regulate manufacturing and impose marketing restrictions during this initial period of FDA Tobacco Center development. This reclassification will eliminate pressure on the several hundred thousand current American users of electronic cigarettes to switch back to the much more hazardous conventional cigarettes.

This year, about 400,000 American adult cigarette smokers will die of a tobacco-related illness. Their second hand smoke will kill about 48,000 non-smokers. About 700 more will die in residential fires. Despite progress on other measures of tobacco use, per CDC estimates, this death count continues to inch up from year to year. In contrast, even though smokeless tobacco products represent about 20% of nicotine intake in the United States, the number of deaths per year from these products is too small for reliable estimates from the CDC.

Our (AAPHP) best estimate is that smokeless tobacco products currently cause about 700 cancer deaths per year in the United States. This is less than 1% of the more than 110,000 deaths that would occur each year if smokeless products carried the same mortality as conventional cigarettes.

This last week, Boffetta and Straif published a paper alleging evidence of an increased risk of fatal heart disease and stroke among smokeless tobacco users. This is a study sure to be referenced by those seeking evidence of

the harmfulness of smokeless tobacco products. Unfortunately, this study suffers from major technical and ethical flaws, including failure to note in the abstract that they found no increased risk of non-fatal heart attack or stroke. Even worse, of the many studies reviewed, only two showed evidence of even a slight increase in risk of death – and these were the ones selected for the conclusion and abstract. That having been said, their allegations of a 13% increase in risk of fatal heart attack and 40% increase in risk of fatal stroke pale in comparison with the 180% to 300% increases in risk for men and women 35-64 years of age posed by smoking conventional cigarettes.

Contrary to prevailing conventional wisdom, virtually all the heart and lung disease from conventional cigarettes, and an estimated 98% of the cancer mortality, are due to direct inhalation of fresh products of combustion deep into the lung. Our best estimate (based on the work of Pankow et al and others) is that only about 2% of the cancer mortality from cigarettes is from the named carcinogens commonly found in tobacco products. Smokeless tobacco products carry little or no risk of heart disease and no risk of lung disease. They do not kill innocent bystanders and they do not burn down houses. The risk of cancer of any kind from smokeless products ranges from a high of about 5% of the risk of cancer posed by conventional cigarettes to a low well under 1% of the risk of cancer posed by conventional cigarettes. While definitive studies have not been done, we have reason to believe that tobacco products, such as electronic cigarettes, consisting of nicotine extracted from tobacco with only trace amounts of other chemical substances, should carry even less risk.

Most of the discussion to date around the new FDA/Tobacco bill has focused on reducing initiation of nicotine use by children and teens. The only discussion of current smokers has been limited to encouraging use of pharmaceutical products to aid cessation. This has been touted as doubling quit rates – but without mentioning that this doubling is from about 3% to about 5% per year. In other words, this option fails 95% of smokers willing to try it, even under study conditions with optimal counseling.

It should be possible to save the lives of 4 million or more of the 8 million adult American smokers who will otherwise die of a cigarette-related illness over the next twenty years. This could be done by making smokers aware of selected smokeless tobacco products (including but not limited to snus and electronic cigarettes) that promise to reduce the risk of tobacco-related illness by 99% or better for smokers who are unwilling or unable to quit. Rather than discouraging nicotine cessation, however, such an approach, even with no medical intervention, would be expected to triple the rate at which current smokers eventually discontinue their nicotine use.

Those writing the new FDA legislation endorsed a harm reduction component to current tobacco control programming, but in a most peculiar way. The law encourages cigarette manufacturers to develop "reduced exposure" products and market them with no scientific proof that such reductions in exposure will reduce risk. The law then requires presumably new "scientific evidence" for smokeless products, already known to be of substantially lower risk. This makes no sense. The law encourages a harm reduction component to current tobacco control programming that might reduce tobacco-related cancer mortality by one or two percent; while actively discouraging switching to lower risk tobacco products that promise to lower total tobacco-related illness and death by 99% or better.

The secret to success, as we see it, will be to add an effective harm reduction component to current tobacco control programming while using the tools made available by this new law to prevent this new harm reduction initiative from increasing the numbers of children and teens who initiate tobacco use.

Reconsidering the FDA stance on electronic cigarettes would be the most logical first step.

We look forward to working with FDA to use the powers granted by this new legislation to rapidly and substantially reduce tobacco-related illness and death, among both current and potential future tobacco users.

References:

The data on smoking attributable deaths on page 2 of this letter are from the Centers for Disease Control MMWR report of November 14, 2008. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm>

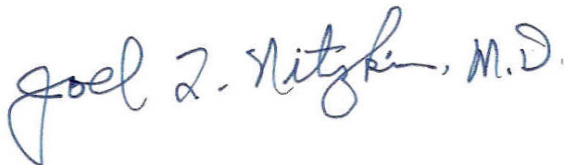
The estimate that 20% of current nicotine consumption in the United States is from smokeless tobacco was generated by Mr. William Godshall, based on the formula utilized by Fagerstrom et al, when estimating 2002 nicotine consumption by type of tobacco product in multiple countries.

The discussion on risk of heart disease and stroke from smokeless tobacco products is from Paolo Boffetta and Kurt Straif : Use of smokeless tobacco and risk of myocardial infarction and stroke: systematic review with meta-analysis. Published August 18, 2009. BMJ 2009; 339: b3060 [Abstract] [Full text]

The data on relative risk of fatal heart attack and stroke from smoking, in men and women 35-64 years of age, are data from the American Cancer Society as quoted in "Changes in cigarette-related disease risks and their implication for prevention and control." Smoking and Tobacco Control Monograph 8. Bethesda, MD: US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute 1997;305-382. NIH Publication no. 97-1213.

The other references to the scientific literature that back-up the points made in this letter can be found on the Tobacco Issues page at the <http://www.aaphp.org> web site. There is an October 2008 "Resolution and White Paper on Tobacco Harm Reduction." This paper, on pages 6 and 13, includes then-current CDC and AAPHP mortality projections. "The Myth of the Safe Cigarette," is based on the paper by Pankow et al (<http://cebp.aacrjournals.org/cgi/reprint/16/3/584>) and others. It makes the case that conventional cigarettes cannot be made measurably safer. The exchange of correspondence with Zhu et al, from a paper published earlier this year, deals with the difference in quit rates, comparing conventional cigarettes to smokeless tobacco products.

Yours,



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Conflict of Interest Disclaimer: Neither of us, nor the American Association of Public Health Physicians, has received or anticipates receipt of any financial support from any tobacco product manufacturer or vendor, or any pharmaceutical firm making nicotine replacement products.