

AAPHP E-cigarette Petitions to FDA – Actions Requested and Justification

Action Requested – Petition to Reclassify E-cigarettes from “Drug Device Combination” to “Tobacco Product”

AAPHP urges the Food and Drug Administration (FDA) to reclassify nicotine vaporizers (E-cigarettes) from “drug-device combination” to “tobacco product.” This reclassification would be limited to E-cigarettes marketed as an alternative to conventional cigarettes for smokers wishing to avoid the toxic substances (other than nicotine) in cigarette smoke.

Since E-cigarettes meet the definition of “tobacco product” under the new FDA/Tobacco law, but do not meet the definition of either cigarette or smokeless tobacco product, **it is our request that they be in a new category of “nicotine vaporizer” with strict FDA regulation of quality of manufacture and marketing, but with warning labels limited to the issue of nicotine addiction.**

Action Requested – Follow-up to July 22,2009 Press Conference

AAPHP urges the Food and Drug Administration (FDA) to follow-up the July 22, 2009 press release and press conference with another press release and press conference to amend certain statements on the basis of new information provided as text and attachments to the two AAPHP petitions being submitted today. The tone and content of the initial press conference left the impression that FDA would not consider either reclassification of E-cigarettes from drug-device combination to tobacco product or consider a related harm-reduction initiative. FDA is urged to review the content of the two petitions with consideration of the possibility that the information herein provided will justify a change in the current FDA stance on these issues.

Justification

This request for reclassification of E-cigarettes from “drug-device combination” to “tobacco product” is based on the following:

Legal: In the mid-1990’s, the Supreme Court blocked FDA’s attempt to regulate tobacco products as drugs and ruled that separate legislative authority would be required for FDA to oversee tobacco products. This was reaffirmed by an opinion expressed by Judge Leon in January of this year, when he excoriated FDA for attempting to regulate E-cigarettes as drugs.

Ethical: FDA priorities are expected to be the protection of the public’s health. Agency decisions are expected to be based on the best available science. FDA should not mislead health-related organizations or the general public as to the health hazard posed by any product. FDA’s current stance relative to E-cigarettes, as presented at the July 22, 2009 FDA press conference, fails on all three of these considerations.

Medical Science and Epidemiology: Even FDA’s own analysis shows E-cigarettes to have the same nicotine with about the same levels of trace contamination found in pharmaceutical products already approved by FDA. Propylene glycol, the other major ingredient is generally recognized as safe. The risk of death attributable to tobacco use from smokeless tobacco products is less than 5%, and, for some products, less than 0.1% the risk of death from conventional cigarettes. The risk of death from E-cigarettes, as best we can estimate from available data, should be about the same as for long term use of pharmaceutical nicotine replacement therapy (NRT) products, at the lower end of this range.

Public Health Impact: Tobacco harm reduction is already well recognized as legitimate in the medical community in terms of long term use of NRT products. Tobacco harm reduction is endorsed by and the new FDA tobacco law in terms of reduced exposure conventional cigarettes. The new harm reduction component recommended in this petition would consist of honest communication to smokers as to the relative risk profiles presented by tobacco and tobacco-related products. On the basis of its review of the medical literature and the unpublished analyses of E-cigarettes presented in this petition, AAPHP has reached three conclusions: 1) reclassification of E-cigarettes as a tobacco product could open the door to a new harm-reduction component to current tobacco control policy; 2) this new harm reduction component presents the only feasible approach to rapidly and substantially reduce tobacco-related illness and death in the United States; and 3) with appropriate regulation of marketing now possible through the new FDA/Tobacco law, the public health benefits of this new harm reduction component could be secured without increasing the numbers of teens initiating nicotine use.

Objections to FDA approval of E-cigarettes as tobacco products are **speculative and largely based on misinformation.**