



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

February 25, 1994

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Vice President for Public Affairs
American Heart Association
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Washington, D.C. 20036

Dear Mr. Ballin:

As you know, the Food and Drug Administration (FDA) has before it several petitions from the Coalition on Smoking OR Health seeking to have FDA regulate low-tar and low-nicotine cigarettes and denicotinized cigarettes as drugs. Rather than respond formally to the petitions at this time, I think it more appropriate to frame the issues for the broader public debate that will be necessary to resolve them.

In its consideration of the petitions, the agency has examined the current data and information on the effects of nicotine in cigarettes. The current data on the highly addictive nature of nicotine and other evidence now available to FDA lead the agency to take a different approach from that urged in the petitions. The structure of the Federal Food, Drug, and Cosmetic Act (the Act), and sound public health policy, suggest that the focus should be on the presence of nicotine in cigarettes in amounts associated with addiction.

As you note in your petitions, FDA has traditionally refrained from asserting jurisdiction over most cigarette products. This has not been based on an interpretation of the Act that cigarettes cannot be regulated as drugs. There is no exemption for cigarettes from the Act's definition of a "drug," and some cigarette products have been regulated as drugs. See United States v. 46 Cartons . . . Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953); United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959).

Under the Act, products are subject to regulation as drugs based on the intent of the product vendor. If the vendor intends that the products be used as drugs (for therapeutic or diagnostic use or to affect the structure or function of the body), FDA may regulate them as drugs. See National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 334-6 (2d Cir. 1977). Although it has been well-known for many years that some people smoke for the drug effects of nicotine (for example, for stimulation and/or to satisfy a dependence on nicotine), cigarette vendors have in the past been given the benefit of the doubt as to whether they

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intend cigarettes to be used for this purpose, because some people smoke for reasons other than the drug effect. See Action on Smoking and Health v. Harris, 655 F.2d 236, 239 (D.C. Cir. 1980).

Evidence brought to our attention is accumulating that suggests that cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction on the part of some of their customers. The possible inference that cigarette vendors intend cigarettes to achieve drug effects in some smokers is based on mounting evidence we have received that: (1) the nicotine ingredient in cigarettes is a powerfully addictive agent and (2) cigarette vendors control the levels of nicotine that satisfy this addiction.

The Coalition is well aware of the large body of scientific evidence documenting the highly addictive nature of nicotine. Most of this evidence is summarized in the 1988 Surgeon General's Report and in the Department of Health and Human Services' 1991 "Triennial Report to Congress on Drug Abuse and Drug Abuse Research." The evidence demonstrates that cigarettes cause an addiction. The current evidence suggests that nicotine, when delivered by cigarettes, produces physiological dependence resulting in withdrawal symptoms when smokers are deprived of nicotine. It also appears that cigarettes enjoy a market that is based in part on the need of smokers to satisfy that addiction. A Canadian survey suggests that 80 percent of smokers believe they are addicted to cigarettes. Other data suggest that a comparable percentage of smokers are, in fact, addicted.

Moreover, the public knows that cigarettes are harmful and many smokers desire to quit. Research has revealed that 77 percent of smokers desire to quit but cannot primarily because of nicotine addiction. At FDA we have approved a number of pharmaceutical therapies for treating nicotine addiction and many more are under development. These therapies, which include nicotine patches and nicotine gum, are essentially, nicotine-delivery systems. There is a growing market for these, as well as non-pharmaceutical, behavioral therapies.

Although technology was developed years ago to remove nicotine from cigarettes and to control with precision the amount of nicotine in cigarettes, cigarettes are still marketed with levels of nicotine that are sufficient to produce and sustain addiction. In fact, it is our understanding that manufacturers commonly add nicotine to cigarettes to deliver specific amounts of nicotine. There is also evidence discovered in recent litigation that some individuals involved in the manufacture of cigarettes in the 1970s regarded their products as nicotine-delivery systems.

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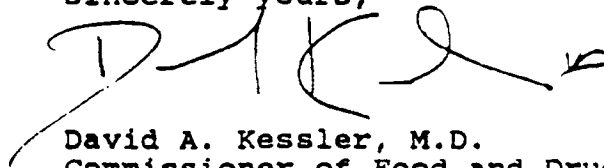
This evidence, along with the growing body of data related to new products proposed for the treatment of nicotine addiction from smoking, suggests that cigarette vendors intend the obvious -- that many people buy cigarettes to satisfy their nicotine addiction. Should the agency make this finding based on an appropriate record or be able to prove these facts in court, it would have a legal basis on which to regulate these products under the drug provisions of the Act.

A strict application of these provisions could mean, ultimately, removal from the market of tobacco products containing nicotine at levels that cause or satisfy addiction. Only those tobacco products from which the nicotine had been removed or, possibly, tobacco products approved by FDA for nicotine-replacement therapy would then remain on the market.

Given the widespread use of cigarettes and the prevalence of nicotine addiction, such a regulatory action could have dramatic effects on our society. One must consider the possible effects of the loss of this source of nicotine on the health of some people who are addicted to nicotine and the possible need for a weaning period. It is also important to consider the potential for a black market in nicotine-containing cigarettes.

We recognize that the regulation of cigarettes raises societal issues of great complexity and magnitude. It is vital in this context that Congress provide clear direction to the agency. We intend therefore to work with Congress to resolve, once and for all, the regulatory status of cigarettes under the Food, Drug, and Cosmetic Act. Few public health issues are more important.

Sincerely yours,



David A. Kessler, M.D.
Commissioner of Food and Drugs

cc: Michael F. Heron, American Cancer Society
Fran Du Melle, American Lung Association
Matthew L. Myers, Asbill, Junkin, and Myers

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