CAMPAIGN for TOBACCO-FREE Kids®

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August 25, 2010

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, RM. 1061
Rockville, MD 20852

Re: Docket No. FDA-2010-D-0281

Ladies and Gentlemen:

The Campaign for Tobacco-Free Kids ("TFK") submits these comments on the Guidance for Industry and FDA Staff in the above-designated docket concerning "Harmful and Potentially Harmful Constituents" in Tobacco Products as used in Section 904(e) of the Federal Food, Drug and Cosmetic Act ("FDCA").

Section 904(e) of the FDCA requires FDA to establish a list of constituents that are harmful or potentially harmful to health. Other provisions of the FSPTCA require manufacturers of tobacco products to report to FDA detailed information about the level of such constituents in each of their brands and sub-brands. The purpose of such reporting is to permit FDA to have current information about the levels of such constituents as the basis for the exercise of its regulatory authorities.

In the guidance issued by the FDA regarding what constituents are encompassed by section 904(e), FDA makes it clear that "harmful and potentially harmful constituents" include not only constituents that are themselves toxic, carcinogenic, or addictive, but also substances that may increase the exposure to the harmful effects of other tobacco product constituents by "(1) potentially facilitating initiation of the use of tobacco products; (2) potentially impeding cessation of the use of tobacco products; or (3) potentially increasing the intensity of tobacco product use (e.g., frequency of use, amount consumed, depth of inhalation)." In addition, the guidance makes it clear that a constituent that "may enhance the harmful effects of a tobacco product constituent" has the potential to cause indirect harm and therefore should be encompassed by section 904(e).

TFK believes FDA's guidance correctly defines the scope of constituents covered by section 904(e). Tobacco products under the authority of FDA kill when used exactly as intended. Thus, constituents that increase the number of users, the intensity of use or decrease the number of people who quit increase the number of people harmed. Constituents that facilitate or may facilitate initiation of the use of tobacco products, decrease or potentially decrease the number who quit, or increase the intensity of tobacco product use cause significant damage to the public health by increasing the exposure of a large number of people to a product whose constituents are toxic, carcinogenic and addictive. This is true even if the constituents are not themselves toxic, carcinogenic or addictive. For example, a constituent that masks the harsh taste of tobacco makes it easier for experimental smokers to continue to smoke until they become addicted and hence increases the number of addicted users of tobacco products. Evidence adduced before the TPSAC concerning menthol indicates that it may facilitate initiation, impede cessation, and increase the intensity of tobacco product use even if it is not itself toxic, carcinogenic, or addictive. In addition, many other substances may have similar effects. Such constituents could have a significant impact on the public health by facilitating initiation, discouraging

cessation, and increasing smoking intensity and their inclusion on the list of harmful or potentially harmful constituents would be consistent with the Congressional mandate.

Moreover, evidence adduced before the TPSAC makes it clear that changes in the level of such constituents can have a significant impact on the number of consumers of tobacco products. Under these circumstances, it is important for FDA to receive information about the level of such constituents in tobacco products because such levels can affect the exposure of many tobacco product users to toxic, carcinogenic and addictive substances.

Although the guidance issued by FDA makes it clear that such constituents are to be included within the scope of section 904(e) and therefore reported to FDA, the TPSAC Subcommittee on Harmful Substances was instructed by FDA staff to limit its consideration of such substances to those substances that were themselves toxic, carcinogenic, or addictive or that enhanced the toxicity, carcinogenicity, or addictiveness of other constituents. Consequently, the list of harmful and potentially harmful constituents compiled by the Subcommittee does not include constituents that cause indirect harm within the meaning of the guidance. The guidance given to the Subcommittee by FDA Staff indicated that the list the Subcommittee would be asked to compile would be more limited than that ultimately developed and promulgated by the FDA.

TFK believes it is important for FDA to make it clear both to the full TPSAC and to the public that the list of harmful and potentially harmful constituents ultimately promulgated will be consistent with the guidance it has promulgated and that the list of substances compiled by the Subcommittee was not intended to be comprehensive of all such substances, but rather was intended to cover only substances that were themselves toxic, carcinogenic, or addictive or which increased the toxicity, carcinogenicity, or addictiveness of other constituents.

Moreover, the statutory requirement that the list include "potentially" harmful constituents means that constituents should be included in the listing required by section 904(e) whenever there is any evidence that they may cause harm or indirect harm; there should not be a requirement of proof that such substances actually cause such harm. The purpose of section 904(e) is to allow FDA to monitor the level of such constituents and therefore the threshold probability that such constituents directly or indirectly cause harm should be low.

Constituents added to tobacco products to increase their consumer appeal are, by definition, additives rather than substances naturally occurring in the tobacco. Thus, it should be simpler for manufacturers to measure the quantities of such additives than it might be to measure quantities of constituents occurring naturally in tobacco or in tobacco smoke.

The list compiled by the Subcommittee includes several constituents that were not themselves considered toxic, carcinogenic, or addictive but which potentially enhanced the addictiveness of the product by affecting the absorption of nicotine (e..g., ammonia). TFK believes the inclusion of such constituents is correct and consistent with the guidance.

TFK urges FDA to adopt processes that will enable it to include in the list of constituents for which reporting is required under 904(e) all constituents for which any evidence exists that they may increase the exposure of users to the harmful effects of other tobacco product constituents.

Sincerely,

Matthew L. Myers

Matthew L. Myers
President
Campaign for Tobacco-Free Kids