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September 8, 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

To Whom It May Concern:

On August 23, Philip Morris USA Inc. and U.S. Smokeless Tobacco Company LLC ("Philip Morris") submitted comments on the above-captioned Draft Guidance that, inter alia, objected to the Draft Guidance because it would require listing of constituents that are harmful or potentially harmful to health because they may promote smoking intensity, encourage smoking initiation, or discourage or interfere with smoking cessation. On August 24, the Campaign for Tobacco-Free Kids ("CTFK") submitted comments on this guidance, drafted before CTFK had read the Philip Morris comments, that endorsed this very aspect of the Draft Guidance. CTFK now submits these supplementary comments in response to the Philip Morris comments.

Section 904(e) of the FSPTCA requires FDA to "establish and periodically revise as appropriate, a list of harmful and potentially harmful constituents, including smoke constituents, to health…by brand and subbrand." Section 904(a)(3) of the FSPTCA requires each tobacco product manufacturer or importer to submit a listing of all constituents, including smoke constituents identified by the FDA as "harmful or potentially harmful to health" in each of its tobacco products by brand and subbrand. Philip Morris argues that the FDA's authority to identify constituents that are harmful or potentially harmful to health—the action that triggers the reporting requirement under section 904(a)(3)-- should be read "narrowly" in accordance with an allegedly narrow Congressional intent, to exclude any listing of constituents that are harmful or potentially harmful to health because they may enhance the addictive properties of tobacco products, promote initiation, or reduce cessation. PM Comments at 2-4. Such a reading would, however, be contrary to the plain language of Section 904(e). As Philip Morris admits, because tobacco products are themselves harmful to health, constituents that enhance their addictiveness, encourage initiation, or discourage cessation are at least "potentially harmful to health." The reading urged by Philip Morris would impose a limitation that is not contained in the actual text of the provision. FDA's Draft Guidance is therefore not an "expansion" of the statutory language as suggested by Philip Morris, but rather a faithful expression of adherence to its plain meaning.

Moreover, the reading urged by Philip Morris would be contrary to the fundamental purposes of the FSPTCA. The Congressional findings explicitly recognize that the Federal Government has a substantial interest in preventing "the life-threatening health consequences associated with tobacco use" Sec. 2 (31) and that "tobacco dependence is a chronic disease that typically requires repeated interventions to achieve long-term or permanent abstinence" and that "because the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely." Sec. 2 (33-34).

Moreover, the Congress specifically found that "the Food and Drug Administration is a regulatory agency with the scientific expertise to identify harmful substances in products to which consumers are exposed." Sec. 2 (44). Having declared that preventing life-threatening health consequences associated with tobacco use and promoting cessation is a legislative objective and that the FDA is the agency with the appropriate expertise to identify the harmful substances that discourage cessation, the Congress is not likely to have intended to prevent the FDA from designating constituents that promote initiation, enhance addictiveness, or discourage cessation as "harmful or potentially harmful to health."

Philip Morris makes three arguments in support of its position. All of them would require the agency to ignore the plain language of section 904(e). First, it argues that the reference in section 904(e) that requires establishment of a list of constituents potentially harmful "to health" should be read "narrowly" because section 904(a)(4) requires manufacturers to submit all documents relating to "health, toxicological, behavorial, or physiologic effects of current or future tobacco products [and] their constituents." (p.3) Philip Morris appears to contend that because section 904(e) does not include the words "toxicological, behavioral, or physiologic" it somehow was intended to exclude constituents that are harmful to health because they enhance addictiveness, encourage initiation, or discourage cessation. No such distinction is tenable. Section 904(a) is indeed broader in its coverage than section 904(e) because it directs the action not of the FDA, but rather of regulated companies and requires regulated companies to submit documents regarding "toxicological, behavioral, or physiologic" effects whether or not they believe such effects are related to health.

In drafting the language of the FSPTCA, the Congress was of course aware of the major tobacco companies' extensive history of deceit and concealment of research. Therefore, in drafting a section directing the companies to submit all research potentially relevant to the agency's regulatory function, it was reasonable for the Congress to have used the broadest conceivable language to ensure that the companies would not make far-fetched arguments to justify withholding of such research. While most toxicological, behavioral or physiologic effects also relate to "health," the "belt and suspenders" language of section 904(a) prevents companies from withholding documents based on arguments that toxicological, behavioral, or physiologic effects could be unrelated to health. By contrast, section 904(e) governs action by the FDA, which is given authority to designate which constituents are harmful or potentially harmful to health either directly or indirectly. Given that section 904(e) was directed at FDA action, there was no need to include the language of section 904(a)(4). The language that was chosen—requiring listing of all constituents found by the FDA to be "harmful or potentially harmful to health"-- is sufficiently broad to cover constituents that may enhance addictiveness, encourage initiation, and discourage cessation.

Second, Philip Morris argues that section 904(e) should be given a narrow reading because other provisions of the statute, such as section 907, relating to the pre-market approval of new tobacco products, section 910 relating to pre-market approval of new tobacco products, and section 911 relating to modified risk products, require that any such standard be "appropriate for the protection of the public health" and explicitly require FDA to consider

(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;
(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and
(III) the increased or decreased likelihood that those who do not use tobacco products will start using products.

Philip Morris argues that the absence of such detailed enumeration of factors from section 904(e) implies that the reference to harmful or potentially harmful effects on "health" should be read narrowly to exclude any listing requirement for constituents that promote addiction, encourage initiation, or discourage cessation. Philip Morris's argument, however, ignores the very large difference between the purpose of section 907 and the purpose of section 904(e). The establishment of product standards under section 907, pre-market approval of new products under section 910 and modified risk products under section 911 involve the exercise of judgment by the agency in balancing interests that may potentially be in conflict. Establishment of some standards may "increase [the] likelihood that existing users of tobacco will stop using [tobacco] products" but yet "increase the likelihood that those who do not use tobacco products will start." For functions that require the exercise of sophisticated judgment about the potential consequences of agency action, the Congress appropriately spelled out the factors to be considered in some detail and—as Philip Morris acknowledges—expressly included effects on addiction, initiation, and cessation as factors to be considered.

By contrast, however, the compilation of a list of products that may be harmful or potentially harmful to health is a far simpler task that requires no such balancing of interests. Addiction, initiation, and cessation all have substantial effects on health. If a constituent may enhance the prospect of addiction or initiation or discourage cessation then it is at least potentially harmful to health. For purposes of section 904(e), the consequence of recognizing this obvious fact is merely that the constituent must be listed. In making this determination there is no reason for the agency to consider the potentially competing interests that would be required for the setting of a product standard. The fact that no such interests are enumerated in section 904(e) does not support a narrow definition of "health" that would exclude constituents that are actually or potentially harmful because they enhance addictiveness, encourage initiation, or discourage cessation.

Third, Philip Morris attempts to make the argument that use of the word "health" in section 904(e) refers to the health of an individual user and therefore differs from references to "public health" elsewhere in the statute. (p.4) It is quite clear, however, that the reference in section 904(e) to "health" does not mean that a constituent must be harmful to any individual or any particular group of consumers. The distinction urged by Philip Morris is meaningless. As long as exposure to tobacco products has adverse health consequences, constituents that enhance addictiveness, encourage initiation, or discourage cessation are "harmful or potentially harmful to health."

The draft guidance promulgated by FDA is fully consistent with the language and the purposes of the statute. The limiting construction urged by Philip Morris is inconsistent both with the language and statutory purpose and should be rejected.

Sincerely,

Matthew L. Myers
President
Campaign for Tobacco-Free Kids