



Harmful and Potentially Harmful Constituents (HPHCs) Suggested Talking Points for Comments to the FDA

Generally speaking, the draft guidance on reporting harmful and potentially harmful constituents in tobacco products would improve public health by requiring greater disclosure of the ingredients of tobacco products to the FDA and to the public. For too long, the tobacco industry has been permitted to sell harmful products to the public with neither the public nor federal regulators knowing what it is in them. This draft guidance is an important first step in correcting this imbalance. Any comments submitted should reflect this, so that there is an administrative record in support of the many strong provisions within the draft guidance. Yet there are ways that the draft guidance could be strengthened. For example:

- The Family Smoking Prevention and Tobacco Control Act requires tobacco manufacturers to submit to the FDA “a listing of all constituents” identified as harmful or potentially harmful in each tobacco product, as well as the quantity of each such constituent in each brand. Along those lines, the FDA has produced a list of 93 harmful and potentially harmful constituents (HPHCs). FDA has made it clear that this list is not exhaustive, but includes only constituents previously identified by other national and international bodies as harmful or potential harmful and includes only constituents linked to some, but not all, tobacco-related diseases. FDA expects the list to be expanded in the future. The current Draft Guidance requires disclosure of only 20 of these 93 constituents, leaving data on 73 of them effectively unreported and therefore outside the scope of effective regulation. FDA should clarify that the policy it has enunciated here is a temporary one designed only to permit regulated companies additional time to develop procedures for full reporting on all harmful and potentially harmful constituents. The constituents as to which reporting requirements have been deferred include such harmful constituents as acetone, hydrogen cyanide, lead, mercury, uranium-235, uranium-238, and polonium-210.
- Moreover, it is essential for FDA to make clear that for purposes of substantial equivalence, new product, and modified risk applications, data on all harmful or potentially harmful constituents will be required.
- The draft guidance states that the disclosure requirements apply only to cigarettes, smokeless tobacco, and roll-your-own tobacco. FDA should promptly act to assert jurisdiction over other tobacco products, such as cigars, electronic cigarettes, and pipes,

so that the disclosure requirements and other requirements are applied to these products. It is essential that the public have knowledge about what is in these products.

- As soon as possible, FDA should convert this guidance into formal regulations, which would be legally binding on manufacturers

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