



## Modified Risk Tobacco Products (MRTPs) Suggested Talking Points for Comments to the FDA

Generally speaking, the guidance document does a good job of ensuring that manufacturers bear the burden of proving every requirement by valid scientific evidence. Indeed, it is largely consistent with the Institute of Medicine report *Scientific Standards for Studies on Modified Risk Tobacco Products*. Any comments submitted should reflect this, so that there is an administrative record in support of the many strong provisions within the draft guidance. For example:

- The tobacco industry has lied for decades about the health effects associated with their products and, as the number and variety of products they produce has increased dramatically, tobacco companies continue to have a strong economic incentive to mislead consumers about the dangers of using their products. Moreover, these misrepresentations have strongly affected consumer perceptions and consumer behavior in the past and caused millions of deaths.
- Overall, the guidance does a good job of tracking the criteria set out in the statute, properly places the burden on the tobacco industry to prove any modified risk claims, and mandates that all decisions take into account the population impact of any claims.
- The guidance appropriately requires manufacturers seeking to make modified risk claims to present scientific evidence about the effect of such claims on consumer perception and on actual consumer behavior.

While it is important to emphasize the strong points in guidance documents, it is also important to mention areas where you believe they could be strengthened. Below are some other issues that you could highlight in your comments.

- As part of an MRTP application, the guidance recommends that manufacturers provide the agency with “copies of any draft promotional materials (e.g., advertising and labeling) *developed by the time of filing* that the applicant expects will be used in marketing the MRTP.” Promotional materials and labeling misrepresenting the health effects of tobacco products have been responsible for misleading consumers and causing massive numbers of preventable deaths. It is a fundamental purpose of Section 911 to ensure that no such claims be made in the future unless they are both true and have been found by the FDA to be beneficial to the health of the population as a whole. Consequently, the agency should require that manufacturers obtain FDA

authorization prior to the dissemination of any promotional materials to be used in marketing the MRTP – including any materials used after the application is approved.

- The draft guidance should require MRTP sponsors to use independent third parties approved by the FDA to design and conduct research, as recommended by the Institute of Medicine.
- As soon as possible, FDA should convert this guidance into formal regulations, which would be legally binding on manufacturers. However, even before formal regulations are issued, FDA should make it clear that applications that do not strictly adhere to the guidance will not be approved.
- MRTP applicant studies should include data on the impact of MRTPs on populations at high risk for tobacco use. FDA should require post-market surveillance for any product allowed to make a claim and insure that the post-market surveillance is sufficient to identify the impact on all sub-populations, including but not limited to youth, other high risk populations, and former tobacco users. The post-market surveillance should include tracking all industry marketing and claims.
- The draft guidance states that the MRTP provisions presently apply only to cigarettes, cigarette tobacco, 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 those products cannot be sold with unproven and misleading health claims. Further, under the Tobacco Control Act, products that are indistinguishable from cigarettes, such as so-called “little cigars,” satisfy the definition of “cigarette.” Many of these “little cigars” are being sold under descriptors such as “light.” The guidance document could clarify that the MRTP provisions apply to “little cigars” because due to their appearance, little cigars are “likely to be offered to, or purchased by, consumers as a cigarette.”

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