FDA Regulation of Tobacco Products: Modified Risk Tobacco Products

The Family Smoking Prevention and Tobacco Control Act (TCA) of 2009 granted the U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products for the first time. The agency now has authority to regulate the manufacture, marketing, sale, and distribution of tobacco products. One of the most critical provisions requires tobacco product manufacturers to receive a marketing order in order to make any modified risk claim about the product. The tobacco industry has a long history of defrauding and misleading the public on the harms of its products. This provision aims to put an end to that practice by requiring manufacturers to prove the truthfulness of any claim.

What are Modified Risk Tobacco Products

The term 'modified risk tobacco product' means any product that is sold or distributed for use to reduce the harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. A product manufacturer can apply to make any of the following claims:

- Disease claim: The tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other tobacco products.
- Exposure claim: The tobacco product or its smoke contain a reduced level of a substance or present a reduced exposure to a substance.
- Exposure claim: The tobacco product or its smoke doesn't contain or is a free of a substance.

Cessation claims, including that a product can help a person quit using tobacco, are medical claims that must be approved by FDA as a medical drug or device. Tobacco products cannot make cessation claims.

FDA Regulation of Modified Risk Products

A manufacturer can submit an application to FDA for a marketing order to make a modified risk claim. That application must include at a minimum:

- A description of the proposed product and any proposed advertising
- The conditions for using the product
- Sample product labels and labeling
- All documents (including underlying scientific information) relating to the research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related disease and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health
- Data and information on how consumers actually use the tobacco product

FDA must make the application available to the public for comment. In addition, the application is referred to the Tobacco Products Scientific Advisory Committee for its review and recommendation.

So-called "Light," "Low," and "Mild" Cigarettes

As health concerns about smoking started to emerge in the 1950s and 1960s, cigarette manufacturers created so-called "light" cigarettes, marketing them as healthier with less tar and less nicotine. Due to the design of these cigarettes, smokers actually smoked longer, inhaling more deeply and more frequently to get their desired dose of nicotine. These design changes may have led to an increase in lung cancers.

Cigarette manufacturers knew these products posed no less risk, yet fraudulently sold them to Americans as such. Decades later, the TCA outright prohibited the terms "light," "low," and "mild."

FDA can only issue a modified risk marketing order if the applicant has demonstrated that the tobacco product, as *used by consumers*, will:

- *Significantly* reduce harm and the risk of tobacco-related disease to the individual; and
- Benefit the health of *the population as a whole* taking into account both users of tobacco products and persons who do not currently use tobacco products.

In other words, the manufacturer must prove there will be a reduction in risk or a benefit to health based on how consumers would actually use the product. Simply stating a product is less harmful without providing information on how consumers would use it would be insufficient.

In issuing a modified risk marketing order, FDA will determine a fixed time period for permitting the claim at which time the application would have to be renewed. In addition, the manufacturer must conduct post-market surveillance and submit annual reports to FDA. FDA has the authority to remove a modified risk product from the market if it is not having the intended public health effect.

Where Are We Now

As of November 2020, FDA has permitted modified risk claims for two products: Swedish Match USA, Inc. snus and Philip Morris Products S.A. IQOS. Swedish Match USA, Inc. is permitted to make a disease risk claim for eight of its snus products, including several mint-flavored products. Philip Morris Products S.A. is permitted to make an exposure risk claim for its IQOS products, including menthol-flavored heatsticks. Philip Morris Products S.A. was denied a disease risk claim. In addition, applications are under review for six R.J. Reynolds Camel Snus products, U.S. Smokeless Tobacco Company's Copenhagen Snuff Fine Cut, and two 22nd Century Group Inc. low nicotine cigarettes.

ACS CAN's Position

ACS CAN, with its tobacco control partners, has opposed the existing and proposed modified risk marketing orders. The applications to date have been insufficient in proving that the products as used by consumers would lead to a reduction in risk. In addition, all the applications have lacked any information on the impact on youth – which is required under the law. In addition, local and state governments should not exempt products that have received a marketing order for a modified risk claim from their tobacco control laws, nor tax them at lower rates than cigarettes and other tobacco products. ACS CAN will continue to comment on these applications and urge FDA to deny any applications that are incomplete and do not meet the standard required by the Tobacco Control Act.