FDA Regulation of Tobacco Products: Premarket Review Requirements

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 powerful provisions of the law is that all new tobacco products must undergo premarket review and receive a marketing order from FDA before the product can be sold legally in the U.S. In practice, the requirement was delayed for over a decade, but went into effect on September 9, 2020.

What is Premarket Review

Products

For new tobacco products, the manufacturer must receive a marketing order from the FDA before the product can be legally sold. A new tobacco product is defined as any product (including those products in test markets):

- that was not commercially marketed in the United States as of February 15, 2007;
- or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

Most e-cigarettes, some cigars and smokeless tobacco, and hookah and pipe tobacco meet the definition of a new tobacco product. In addition, any future tobacco product or change to an existing tobacco product is likely to meet the definition of a new tobacco product.

Public Health Standard

Because the FDA's traditional standard of "safe and effective" for food and drug products cannot apply to tobacco products, the TCA established a new standard of "appropriate protection of public health" (the public health standard). The standard must take into account:

- Risks and benefits to the population as a whole, including people who would use the proposed new tobacco product as well as nonusers;
- Whether people who currently use any tobacco product would be more or less likely to stop using such products if the proposed new tobacco product were available; and
- Whether people who currently do not use any tobacco products would be more or less likely to begin using tobacco products if the new product were available.

Process

Tobacco product manufacturers' applications must include information on known or potential health risks, ingredients, additives, and other components, manufacture and processing, samples, and any other information the FDA requests. The FDA must use the public health standard in making a determination on whether to issue a marketing order and has the option of submitting the application to the Tobacco Products Scientific Advisory Committee for review. Marketing orders are issued on a product by product basis.

Importantly, the FDA does *not* approve applications or products to the marketplace. The TCA prohibits manufacturers from explicitly and implicitly saying that their product has been approved by the FDA.

Delays in Premarket Review

Two types of delays have led to a marketplace full of products that are now considered illegal because they lack a marketing order from FDA. The first was the delay in finalizing the deeming rule and the second was FDA's own decisions to delay enforcement of the premarket review application requirements.

The TCA granted FDA the authority over cigarettes, roll-you-own tobacco, and smokeless tobacco immediately in 2009 and stated that the FDA could deem all other tobacco products under its authority through rulemaking. The FDA did not finalize its "deeming" rule until 2016. Meanwhile, from 2009 to 2016, the U.S. marketplace was flooded with new tobacco products that did not fall under FDA's jurisdiction until publication of the final deeming rule.

The FDA recognized that it could not enforce pulling all the newly illegal tobacco products off the market when the rule took effect. Instead, as part of the rule, the FDA created a compliance period of up to three years for products to stay on the market if manufacturers submitted their premarket review applications. Then in 2017, FDA made the decision to permit these products to stay on the market virtually indefinitely.

The result of these delays is thousands of products on the market illegally because they meet the definition of a new tobacco product and do not have a marketing order from FDA.

Where Are We Now?

ACS CAN and its public health partners successfully sued the FDA over its decision to permit newly illegal products to stay on the market virtually indefinitely. In deciding for public health groups, U.S. District Judge Paul W. Grimm found that the FDA had exceeded its legal authority by not carrying out its statutory mandate to review these products, and the FDA's delay had played a role in the skyrocketing youth use of e-cigarettes. Judge Grimm ruled that the FDA's delay gave "manufacturers responsible for the public harm a holiday from meeting the obligations of the law."

The court set a deadline of May 12, 2020 for all manufacturers of new tobacco products to submit their premarket review applications. That deadline was later extended to September 9, 2020, due to the COVID-19 pandemic. Manufacturers of products that did not submit applications by the deadline are subject to FDA enforcement to remove the products from the market, and those that did submit applications can keep the products on the market for up to one year while the FDA considers the applications. Importantly, FDA has indicated it will use its enforcement discretion in implementing product reviews, which could lead to further delays. Unfortunately, in a separate legal case brought by the industry, a judge ruled that FDA had not properly regulated premium cigars, so those products are not currently required to submit new product applications.

To date, FDA has issued marketing orders for eight smokeless products manufactured by Swedish Match North America, Inc, one heated product with three stick varietals known as IQOS with Headsticks manufactured by Philip Morris Products S.A. and a low nicotine cigarette with tobacco- and menthol-flavored varietals known as Moonlight manufactured by 22nd Century Group Inc.

ACS CAN's Position

ACS CAN advocated for premarket review of all new tobacco products as one of the key components of the TCA to prevent the marketing of products unless the manufacturer has submitted scientific information that the product would be "appropriate for the protection of the public health." The delay in implementation of premarket review represents an extraordinary departure from the requirements under the law and has allowed manufacturers to freely continue to market these products in ways that appeal to youth. It is critically important that FDA quickly and effectively implement review of all new products.

As FDA begins to implement premarket review it must make enforcement a priority. FDA must ensure resources are sufficient to effectively monitor compliance with the law, remove products that remain illegally on the market, provide a swift response to violations, and establish collaborations with other federal agencies, states and localities, and non-governmental organizations when appropriate. States, localities and the public also have a role in ensuring the effectiveness and enforcement of premarket review by monitoring the effects of the products on the market and ensuring they do not fuel the youth epidemic of e-cigarette use.