FDA's Final Deeming Rule On Other Tobacco Products

Implementing The Family Smoking Prevention and Tobacco Control Act

The Family Smoking Prevention and Tobacco Control Act (TCA) – signed into law by President Obama in 2009 - granted the U.S. Food and Drug Administration (FDA) authority to regulate the manufacture, marketing, and sale of tobacco products. Prior to the law, tobacco products were largely unregulated outside of required warning labels and limited restrictions on advertising.

On May 5, 2016, the FDA released its final rule deeming all tobacco products, including cigars, electronic cigarettes (or e-cigarettes), and hookah, as being under its authority granted by Congress in the TCA. Prior to this date, only cigarettes, roll-your-own-tobacco, and smokeless tobacco were subject to regulation under the TCA. Additionally, the rule applies three specific provisions to the newly deemed tobacco products for the protection of public health. ***The Final Rule can be found here.***

Deeming

Under the final rule, the FDA is bringing all categories of tobacco products, including certain dissolveables, gels, hookah tobacco, e-cigarettes, cigars, pipe tobacco, and all future tobacco products under its authority. There are several provisions of the TCA that these products will be subject to when the final rule takes effect in August 2016. These include:

Requiring tobacco industry registration, product listing, and disclosure of contents of tobacco products, research, and marketing information to the FDA: Tobacco product manufacturers are required to disclose to the FDA all product and smoke ingredients, additives, and byproducts. In addition, the industry is required to disclose any documents related to the health, toxicological, behavioral, or physiological effects of their products, and marketing information. The FDA has published the list of harmful and potentially harmful constituents that tobacco product manufacturers must report if they are in their products. The rule also clarifies that establishments that mix or prepare e-liquids or create or modify aerosolizing apparatus for sale to consumers meet the definition of tobacco manufacturers and are subject to the TCA.

Prohibiting the use of all unsubstantiated health claims: Tobacco product manufacturers are required to prove any so-called modified risk or reduced-harm claim for a tobacco product through an application to the FDA prior to using the claim in marketing and advertising. Additionally, misleading descriptors such as "light," "low," and "mild" are prohibited.

Applying a new "public health standard" for tobacco product regulation: Because the FDA's traditional standard of making foods and drugs "safe and effective" cannot apply to tobacco products, the law established a new standard of "appropriate protection of public health." The standard must take into account: risks and benefits to individuals and the population as a whole, including tobacco product users and nonusers, whether current users would be discouraged from quitting and whether current non-users would be encouraged to start. The FDA will use the standard for:

- **Premarket review of new tobacco products:** For new tobacco products that are not substantially equivalent to a product already on the market, the manufacturer must receive an order from the FDA before the product can go to market. Recognizing that many of these newly deemed products

are currently on the market, the FDA has established compliance periods that allow these products to stay on the market if the manufacturer submits its premarket application during that time. The product must be removed from the market at the end of that compliance period if an application was not submitted, or if an application was submitted and the FDA determined not to issue a marketing order or if the FDA took no action.

- **Requirements for tobacco product changes:** The FDA can require changes to tobacco products, such as removal of harmful ingredients, elimination of flavors, or reduction of nicotine levels, in order to make tobacco products less harmful, addictive, or appealing.

Prohibiting the distribution of free samples of all newly deemed products. This rule extends the prohibition of free samples of cigarettes to all newly deemed tobacco products. Distribution of free samples of smokeless tobacco remains restricted.

Establishing enforcement actions that can be taken regarding products determined to be adulterated or misbranded. Adulterated or misbranded products include those that are not in compliance with the law, including good manufacturing practices, labeling and product standards, and premarket review.

Three Specific Provisions

In addition to "deeming," the FDA finalized three specific provisions be applied to newly deemed tobacco products.

(1) Prohibiting retailers from selling newly deemed tobacco products to persons under the age of 18 and requiring photo identification;
(2) Prohibiting the sale of newly deemed tobacco products from vending machines, except in adult-only facilities; and
(3) Requiring warning statements on products and advertisements. Specifically, newly deemed tobacco products will be required to have the warning statement: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." Cigar manufacturers will continue to rotate the five existing Federal Trade Commission required warnings with this new addiction warning. The warning statements will be required to appear on products and advertisements 24 months after publication of the final rule, with a 30-day grace period for any remaining inventory.

The final rule does not address the marketing or advertising of or flavorings in these products.

State and Local Authority

The TCA preserves the authority of states and localities to implement smoke-free policies, tobacco taxes, and to further restrict "the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards" for tobacco products in their communities. The preservation of state and local authority is reinforced in the final rule and makes the statement that "No State or local laws

in effect at the close of the public comment period were identified that FDA determined would be preempted by this final rule."

While the TCA preserves state and local authority to restrict the advertising and promotion of tobacco products, decisions by the US Supreme Court and some Circuit courts have struck down numerous advertising restrictions imposed by states and localities based on the First Amendment. Unfortunately, the new rule cannot impact the validity of these decisions.