Federal Update: March 30, 2018

Health Groups File Suit to Expedite FDA Review of E-Cigarettes, Cigars

In August 2016, the Food and Drug Administration (FDA) released a new rule, known as the "deeming rule." This new rule would extend the FDA's jurisdiction to e-cigarettes, cigars and other previously unregulated tobacco products. In August 2017, the FDA delayed a key provision of that rule which would have required manufacturers of products then on the market to provide critical information to the FDA about each product, therefore undergoing an FDA review of the product's impact on public health, including whether certain products would appeal to children. The FDA delayed the deadline for filing applications until August 2021 for cigars and newly-regulated combustible products and until August 2022 for e-cigarettes. According to the FDA these products will remain on the market indefinitely during the review process and did not set a deadline for completing its review.

The Lung Association was one of seven public health, medical groups, and several individual pediatricians that filed suit on March 27, 2018 in federal court in Maryland challenging the FDA. Although the groups strongly support the FDA's new efforts to reduce nicotine levels in cigarettes to minimally or non-addictive levels, they also believe that the FDA's decision leaves on the market tobacco products that appeal to kids, deprives the FDA and the public of critical information about the health impact of products already on the market, and relieves manufacturers of the burden to produce scientific evidence that their products have a public health benefit.

The need for the FDA to review e-cigarettes now on the market has been underscored by the recent surge in popularity of JUUL, which has become the best-selling e-cigarette brand and is reported to be widely used by teens. JUUL e-cigarettes look like USB flash drives; they are sold in flavors that include mango, crème brulee and various fruit medleys and each cartridge contains as much nicotine as a pack of cigarettes. Despite all these reports, the FDA has taken no action regarding JUUL.

The health groups' lawsuit contends that the FDA's lengthy delay of product review deadlines exceeds the agency's authority under the Family Smoking Prevention and Tobacco Control Act. This also contends that the FDA's decision violates the Administrative Procedure Act because the FDA did not give the public an opportunity to comment on the change and did not articulate an adequate factual basis for this change from the deadlines the FDA established in the deeming rule.

To read the American Lung Association's full press release regarding the corrective statements, please click HERE.

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If you have questions about this analysis, please contact Emma Maron (emma.maron@lung.org).

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