Issue Snapshot on Deeming: Regulating Additional Tobacco Products

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), signed by the President in 2009, created the FDA Center for Tobacco Products and gave FDA powerful tools to protect the public's health through our oversight of the manufacture, distribution, and marketing of tobacco products. Under the law, FDA currently regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products. The law also gave FDA the ability to regulate additional tobacco products, commonly referred to as "deeming" them through rulemaking. The proposed rule would include the following products under FDA's authority: electronic cigarettes (e-cigarettes), cigars, pipe tobacco, waterpipe (hookah) tobacco, and novel products like nicotine gels and dissolvables not already under FDA's authority. FDA's proposed rule also would include tobacco product components or parts that are used in the consumption of a tobacco product, like e-cigarette cartridges. It would not include tobacco product accessories, like cigar cases.

Why the Deeming Proposed Rule Is So Important for Public Health

With the release of the 50th Anniversary Surgeon General's Report on Smoking and Health, we now know that the annual death toll from tobacco-attributable disease has risen to more than 480,000. At this rate, there will be more than 17 million deaths from tobacco use between now and mid-century. Additionally, youth use of certain unregulated tobacco products, such as e-cigarettes and cigars, is on the rise. FDA oversight of tobacco products can provide important information about proposed deemed tobacco products and help limit youth exposure to these products. The proposed rule would also enable FDA to explore whether different products pose different levels of risk, and would help the Agency develop policies to improve public health.

Highlights of the Deeming Proposed Rule

Consistent with currently regulated tobacco products, under the proposed rule, makers of newly deemed tobacco products would, among other requirements:

- Register with FDA and report product and ingredient listings
- Only market new tobacco products after FDA review
- Only make claims of reduced risk if FDA confirms that scientific evidence supports the claim and that marketing the product will benefit public health as a whole
- Not distribute free samples

In addition, under the proposed rule, the following items would apply to newly deemed covered tobacco products:

- Minimum age and identification restrictions to prevent sales to underage youth
- Requirements to include health warnings
- Prohibition of vending machine sales, unless in a facility that never admits youth

The term "covered tobacco products" is defined here as those products deemed to be subject to the Food, Drug, and Cosmetic Act under section 1100.2 of title 21 of the Code of Federal Regulations (CFR), other than a component or part that does not contain tobacco or nicotine.

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CENTER FOR TOBACCO PRODUCTS