FDA's "New Approach" to Nicotine: Why Retreat from the Deeming Rule?

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FDA's "New and Comprehensive Approach" to Nicotine Regulation: Key Premises

- Harm from nicotine tobacco products determined by delivery mechanism
- Continuum of risk of nicotine delivery, from medicinal nicotine (least dangerous) to combustible products (most dangerous)
- Need for innovation to develop less harmful nicotine products to cause smokers to switch

New FDA Approach: What's Promising

- Reducing nicotine in cigarettes to non-addictive levels

- Movement on flavored products, including menthol in cigarettes

- Coordinated agency-wide effort toward more effective therapeutic products

New FDA Approach: Retreat from the Deeming Rule

- Immediate extension of compliance deadlines for new product review of cigars, e-cigarettes and other newly-regulated products under deeming rule
  - Five years (to 2021) for cigars
  - Six years (to 2022) for e-cigarettes

- Threat of “premium cigar” exemption from deeming rule