The Nicotine Scene: PMTAs, Pouches, and Policy

Intro (0:00 – 01:40 min)

Main Content (1:40 min – 40:40 min)

- Overview of FDA's Regulation of Tobacco and Nicotine Products (1:40 min – 7:07 min)
    - Tobacco Control Act and the 2016 and 2022 expansions of the definition of "tobacco product"
    - FDA's 2016 Deeming Rule (ENDS products and pouches)
    - Premarket authorization requirements (PMTAs) and deferred enforcement policies
    - Shift from anticipating FDA's next moves to navigating PMTAs and compliance
    - FDA's New ENDS and Nicotine Pouch Enforcement Guidance: Lower Priority for Post-November 2021 Reviewable Applications, Higher Scrutiny for Illicit Products | The Continuum of Risk
- Tobacco and Nicotine Product Authorizations (7:07 min – 13:13 min)
    - PMTA process for vapes, pouches, etc. (newer categories of products) and other pathways to premarket approval, like substantial equivalence
    - Standard to prove products are Appropriate for the Protection of Public Health (APPH)
    - Tobacco Control Act vs. Safety and Effective Standard
    - Flavored Products and the associated regulatory challenges
    - FDA Authorizes Modified Risk Claims for ZYN Nicotine Pouches: A Landmark Step for Tobacco Harm Reduction | The Continuum of Risk
- Most Significant Litigation Trends (13:13 min – 19:43 min)
    - 2020 Compliance Policy deadline to avoid FDA enforcement against unauthorized products
    - Mass denials of flavored ENDs products due to presumption of youth smoking risk
    - FDA's Comparative Efficacy Requirement
    - *FDA v. Wages and White Lion Investments, L.L.C.* — Supreme Court Decision (July 2025)
- FDA's New Guidance Documents in 2026 (19:43 min – 32:33 min)
    - Draft guidance on flavored ENDS; creates tiers of flavors based on associated risk levels
    - Regulatory actions resulting in falling youth tobacco use and vaping rates; this trend affects arguments made by companies
    - FDA prioritizing enforcements differently
        - Focus on illicit products versus unauthorized products already on the market

        - Make public list of products that meet filing status
    - Incentive to participate in PMTA process
    - Proposed rule for enforcement at the border and requirements for foreign manufacturers to register with FDA
    - FDA Formalizes a Flavor-Specific PMTA Framework as Youth Vaping Continues to Decline | The Continuum of Risk
- Recent Developments in the Tobacco Authorization Space (32:33 min – 40:40 min)
    - FDA Authorizes Glas Flavored ENDS Products, Opening an Age-Gating Pathway for Flavors | The Continuum of Risk
        - First ever non-menthol, non-tobacco flavored product to be authorized
        - Age-gating technology as key pathway to approval and evidence of mitigating youth risk
    - Challenges of oral nicotine products (pouches)
        - Notably not a youth issue with this product category
        - FDA Issues First Marketing Authorization for Oral Nicotine Pouches | The Continuum of Risk
        - FDA Authorizes Modified Risk Claims for ZYN Nicotine Pouches: A Landmark Step for Tobacco Harm Reduction | The Continuum of Risk
    - Large number of companies pursuing PMTAs because of various recent product authorizations

Upcoming Keller and Heckman Events

- Seminar on September 22 – 23, 2026 - 2026 Practical Primer on Pesticides | Keller and Heckman
- Seminar on October 6 – 7, 2026 - Navigating TSCA: Basics and Beyond 2026 | Keller and Heckman
- Seminar on October 27 – 28, 2026 - 2026 Annual Food Packaging Law Seminar | Keller and Heckman