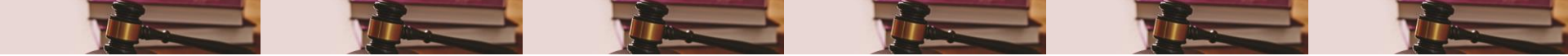

An Update on Tobacco Litigation and Enforcement Actions

J. Benneville (Ben) Haas, Partner, Latham & Watkins LLP

Eric Heyer, Partner, Thompson Hine LLP

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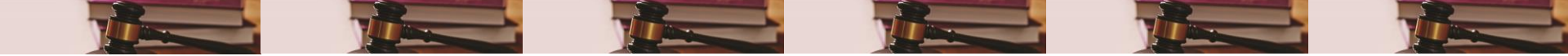

Tobacco Litigation Update

Eric N. Heyer

Thompson Hine LLP

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Disclaimer

- The information presented is for educational and informational purposes only and not for the purpose of providing legal advice.
- You should contact your attorney to obtain advice with respect to any particular issue or problem discussed during this presentation.
- Participation in this presentation does not create an attorney-client relationship between Thompson Hine LLP and you.
- The opinions expressed during this presentation are the opinions of the individual author.

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Deeming Rule Litigation

- ***Nicopure Labs v. FDA***
  - Deeming Rule and Free Sample Ban Upheld by D.C. Circuit
- ***Big Time Vapes, Inc. v. FDA***
  - Filed August 19, 2019, in Southern District of Mississippi
  - Motion for preliminary injunction filed October 10, 2019, and now fully briefed
  - Claim is that Congress unconstitutionally delegated legislative power to FDA when it allowed FDA to "deem" products other than cigarettes, cigarette tobacco, RYO tobacco, and smokeless tobacco to be "tobacco products" without providing parameters, guidance, or factors governing the exercise of that discretion
  - Relies on *Nicopure* district court's finding that "the statute did not provide a standard for when and how the agency was to exercise its discretion to deem"
  - FDA contends the Tobacco Control Act, taken as a whole, sets down an "intelligible principle" to which FDA was required to conform

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PMTA-Related Litigation

- ***American Academy of Pediatrics v. FDA***
  - filed in District of Maryland
  - challenged August 2017 FDA guidance extending PMTA deadline for newly deemed products, including cigars and ENDS
  - summary judgment entered in favor of plaintiffs on May 15, 2019
  - remedy ruling on July 12, 2019 – sets highly accelerated 10-month PMTA deadline and cites —cites "extraordinary circumstances" of youth vaping "epidemic" as justification to avoid merely remanding

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PMTA-Related Litigation

- ***American Academy of Pediatrics v. FDA***
  - court rejects request that it enjoin FDA to take enforcement action against manufacturers that fail to meet deadline
  - FDA initially fails to take appeal, but ultimately does after leave to intervene granted to industry groups to do so
  - although lawsuit focused on ENDS, accelerated deadline equally applicable to cigars and other newly deemed products
  - motion to stay pending ruling on appeal expected imminently

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PMTA-Related Litigation

- ***Vapor Technology Association v. FDA***
  - filed August 14, 2019 in the Eastern District of Kentucky
  - preliminary injunction motion filed on September 2, 2019; now fully briefed
  - focus is on CTP Director Zeller's suggestion in *American Academy of Pediatrics* that a 10-month PMTA deadline would be appropriate; contradicts two years of FDA public statements saying "foundational rules" needed first
  - seeks declaratory judgment that FDA violated APA and manufacturers' due process rights because of reliance interests and an injunction preventing FDA from taking enforcement action against manufacturers who fail to submit "high quality" PMTAs by May 2020
  - FDA's opposition and motion to dismiss based primarily on justiciability and standing grounds

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PMTA-Related Litigation

- ***Cigar Association of America v. FDA***
  - filed July 15, 2016, in the United States District Court for the District of Columbia
  - motion for summary judgment that August 2017 Guidance remained in effect for SE reports for cigars *post-AAP* denied on October 18, 2019, because:
    - ✓ Plaintiffs failed to satisfy causation and redressability prongs for Article III standing
    - ✓ Anticipated future enforcement action against products as "misbranded" too speculative
    - ✓ Judge Grimm in *AAP* explicitly confirmed that his ruling covered cigars as well as ENDS products
    - ✓ Relief would constitute a collateral attack on Judge Grimm's order
    - ✓ Equitable and prudential factors weighed against declaratory relief because Plaintiffs and FDA agreed that August 2017 Guidance was a permissible exercise of agency enforcement discretion

PMTA-Related Litigation

- A fundamental question common to all PMTA deadline-related litigation with implications for a potential deemed products flavor ban:

  Was FDA's August 2017 Guidance:

  (1) A proper exercise of agency enforcement discretion? (FDA and Cigar Association of America's view)

  (2) A modification of a legislative rule first promulgated in the Deeming Rule itself? (Vapor Technology Association's view)

  (3) An unlawful abdication of FDA's statutory obligations? (Public Health Groups and Judge Grimm's view)

State Flavor Ban Litigation

- From mid-August to mid-October, several states imposed emergency flavor ban regulations on ENDS products:
  - Michigan
  - New York
  - Massachusetts
  - Rhode Island
  - Washington
  - Oregon
  - Montana
  - Utah (for general retailers only)

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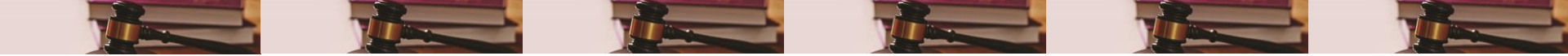

State Flavor Ban Litigation

- Cited bases were youth vaping “epidemic” and severe respiratory illnesses
- Legal challenges have been brought in each state on various grounds:
  - ✓separation of powers
  - ✓Commerce Clause
  - ✓administrative procedure defects
  - ✓First Amendment

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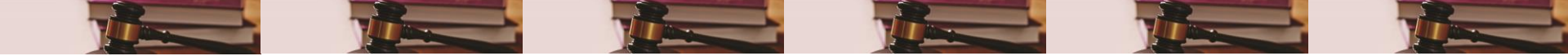

State Flavor Ban Litigation

- Temporary Restraining Orders and injunctions have been obtained in:
  - ✓New York
  - ✓Michigan (post-implementation)
  - ✓Oregon
  - ✓Montana
  - ✓Utah

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State Flavor Ban Litigation

- Flavor bans remain in effect in:
  - Washington
  - Rhode Island
  - Massachusetts (now via legislation)
- Belated CDC acknowledgment (on November 8) that severe respiratory illnesses appear tied to vitamin E acetate in illicit THC pods appears to have stemmed the tide of further state flavor bans.
- But, local flavor bans via legislation continue, including in New York City.

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State Attorney General Investigations

- New York, Connecticut, Maryland, Massachusetts, Illinois, and Florida attorneys general investigating ENDS manufacturers and online vaping retailers for:
  - false advertising
  - marketing practices targeting minors
  - sales to minors without proper age or identity verification

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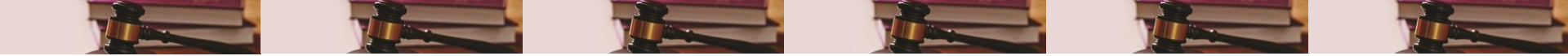
State Attorney General Litigation

- Various state attorneys general have filed lawsuits against JUUL for allegedly deceptive marketing practices targeting minors:
  - North Carolina
  - New York
  - California
  - District of Columbia



Municipal Lawsuits

- Chicago and New York City lawsuits have targeted:
  - ENDS manufacturers and distributors
  - e-liquid manufacturers
  - online vapor products retailers
- City of Chicago lawsuit filed in November 2018 premised on violations of unfair trade practices ordinance
- New York City lawsuit filed in October 2019 premised on allegations of public nuisance created by youth vaping epidemic

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Municipal Lawsuits

- Claim is that Defendants have engaged in unfair and deceptive trade practices or created a public nuisance by:
  - engaging in sales to minors
  - using social media and other advertising that targets minors
  - selling e-liquid flavors that are targeted toward minors

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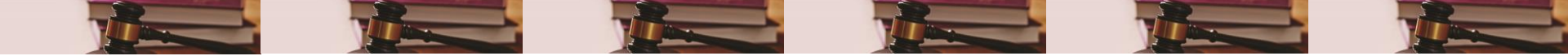

Tobacco Litigation Update

Questions?

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Update on Tobacco Enforcement Actions

Ben Haas

December 12, 2019

Agenda

- How does OCE enforce the TCA?
- How does OCE identify violations?
- Current enforcement priorities
- Limitations on OCE
- Current enforcement landscape
- Other sources of TCA enforcement (federal, state, local)

OCE Enforcement Toolkit

- FDCA permits OCE to utilize several approaches to enforcement:
  - Advisory Actions
    - Untitled letters
    - Warning letters
  - Administrative Actions
    - Civil monetary penalties (CMPs)
    - No-tobacco-sale orders (NTSOs)
  - Judicial Actions
    - Seizures
    - Injunctions
    - Criminal prosecutions
- Secure Voluntary compliance
  - Twitter / compliance policies / announcements
  - Industry outreach and engagement

OCE Enforcement Toolkit

- How does OCE identify violations?
  - Retail inspections
  - Website monitoring and surveillance
  - Social media
  - Manufacturing (including vape shop) inspections
  - Attendance at “promotional events”[22]

OCE Priorities

- Youth Tobacco Prevention Plan
  - Prevent youth access to tobacco products
    - Retail inspections
    - Targeting of flavored products through publicity
    - Engagement with major manufacturers
  - Limit marketing of tobacco products to youth
    - Eliminating enforcement discretion for products with youth appeal
    - Collecting sales and marketing information from manufacturers
    - Warning letters

OCE Bases for Enforcement (limitations)

- Section 906(d) regulations governing sale and distribution; advertising and promotion
  - "appropriate for the protection of the public health"
  - Advertising restrictions "consistent with and to the full extent permitted by the First Amendment"
  - Remote sales (March 2011 ANPRM)
- Section 907 Tobacco Product Standard
  - Tobacco product standard requiring the reduction or elimination of constituents/ingredients (e.g., flavors)
    - Must account for technical achievability
    - Must account for potential contraband
  - Lengthy process (notice-and-comment rulemaking; at least 1 year delayed effective date)
  - March 2018 ANPRM re: regulations of flavors in tobacco products
- Section 911
  - Prohibition on "modified risk" claims
- Prohibition on "adulteration" and "misbranding" (false and misleading claims)

OCE Bases for Enforcement

- Section 905(j) and 910 Premarket Review
  - Significance of February 15, 2007 and August 8, 2016 dates
  - “Ban” or change in enforcement priorities? What does that mean?
  - PMTA
    - PMTA Order may impose sale and distribution restrictions “only to the extent” permitted under 906(d)
    - FDA wants PMTAs to propose specific restrictions on sale and distribution in order make the APPH showing necessary for approval
    - IQOS Order placed “stringent restrictions” on marketing, particularly on the internet/social media
      - Lengthy memo issued in connection with approval provides roadmap for future applicants
      - Significant recordkeeping and reporting obligations
- Nicotine Warnings

OCE Bases for Enforcement

- Tobacco products marketed with drug claims are regulated as drugs
- Products which are intended to diagnose, cure, mitigate, treat or prevent disease are regulated as drugs
- For example, nicotine replacement therapies (NRTs) require approval through a New Drug Application
- FDA coordinates with the Federal Trade Commission, with which it shares jurisdiction over tobacco products

Current Enforcement Landscape

- All deemed products that are not grandfathered are putatively unlawfully marketed
  - Oct. 2018 letters to 21 manufacturers requesting evidence of marketing
- Subject to FDA enforcement discretion as announced in Deeming Rule and subsequent compliance deadlines guidance documents, provided premarket submissions are timely filed
- In March 2019, FDA issued draft guidance which, if finalized, would revise the agency's compliance policy to prioritize enforcement for:
  - Flavored cigars
  - Flavored ENDS products (other than tobacco-, mint-, and menthol-flavored) "offered for sale in ways that pose a greater risk for minors to access such products"
  - All ENDS products that "are targeted to minors or likely to promote use of ENDS by minors"
- FDA has yet to issue final guidance

Current Enforcement Landscape

- FDA enforcement actions to date has largely reflected its youth access prevention priorities
- Joint FDA/FTC Warning Letters issued to several manufacturers and distributors of 'kid-attractive' e-liquids resembling juice boxes, candy, or cookies
  - Letters pursuant to FDCA's misbranding provision and FTC's unfair and deceptive marketing authorities
- May 2018 FDA requests for youth access prevention information from certain e-cigarette manufacturers
  - Solicited plans "describing how [each company] will address . . . youth access and use of their products."
- September 2019 Warning Letter to Juul Labs alleging violation of Section 911 modified risk tobacco product provisions
  - Did not address premarket authorization provisions

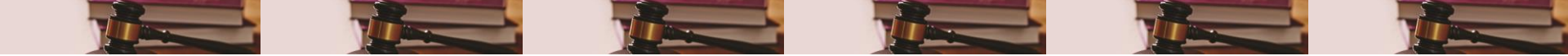
Current Enforcement Landscape

- "FDA has determined that JUUL adulterated its products… by selling or distributing them as modified risk tobacco products without an FDA order in effect that permits such sale or distribution."
- "Referring to your ENDS products as '99% safer' than cigarettes, 'much safer' than cigarettes, 'totally safe,' and 'a safer alternative than smoking cigarettes' is particularly concerning because these statements were made directly to children in school. Our concern is amplified by the epidemic rate of increase in youth use of ENDS products, including JUUL's products, and evidence that ENDS products contribute to youth use of, and addiction to, nicotine, to which youth are especially vulnerable."

FDA Warning Letter to JUUL Labs (Sept. 9, 2019)

Parallel Enforcement

- Other federal authorities also may inform enforcement landscape
- In October 3, 2019, FTC issued orders to six e-cigarette manufacturers
  - Seeking information and documents related to sales, advertising and promotional practices
- Congressional hearings
  - In 2019, youth access related hearings in the Senate's Committee on Health, Education, Labor & Pensions; House Committee on Energy & Commerce; House Committee on Oversight & Reform's Subcommittee on Economic and Consumer Policy
  - Testimony from hearing cited in FDA's September 2019 Warning Letter to Juul Labs
- State and Local bans
  - TCA preemption: No state or locality may establish requirement different from, or in addition to, provision relating to "tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products"



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