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E-Cigarettes and FDA Enforcement

FDLI Conference- FDA Regulation of Tobacco Products

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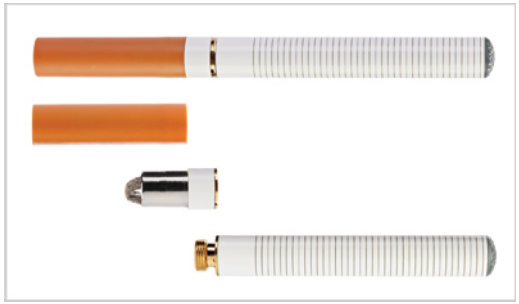
Jonathan A. Havens
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, D.C. 20004
(202) 739-5952
jhavens@morganlewis.com

FDA Regulation of E-Cigarettes

- Currently, FDA, though the Center for Tobacco Products (CTP), regulates
  - cigarettes,
  - cigarette tobacco,
  - roll-your-own tobacco, and
  - smokeless tobacco
- FDA's proposed "deeming regulation" would extend the Agency's tobacco authority to cover additional products that meet the Family Smoking Prevention and Tobacco Control Act's definition of a tobacco product (*e.g.*, e-cigarettes)
  - For a full analysis of the proposed rule, *see* Morgan Lewis LawFlash, "FDA Proposes Tobacco Products Rule; E-Cigarettes, Cigars To Be Regulated" (April 25, 2014), *available at* http://www.morganlewis.com/pubs/LifeSci_LF_FDAProposesTobaccoProductsRule_25april14.pdf
- So what is the current status of FDA e-cigarette regulation?

Regulation of E-Cigarettes as Tobacco Products- The *Sottera* Decision

- Between 2008 and 2010, FDA determined that certain e-cigarettes were unapproved drug/device combination products and detained and/or refused admission to those offered for import
- Sottera, Inc. challenged that determination in court. *See Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010).
- The D.C. Circuit held that e-cigarettes and other products made or derived from tobacco can be regulated as "tobacco products" under the Act and are not drugs/devices unless they are marketed for therapeutic purposes.
  - *e.g.*, smoking cessation claims



Enforcement Based on Marketing Claims

- The *Sottera* decision states that products made or derived from tobacco can be regulated under the Tobacco Control Act unless they are "marketed for therapeutic purposes," in which case they are regulated as drugs and/or devices
- While FDA intends to regulate e-cigarettes as tobacco products, what if an e-cigarette manufacturer markets its product as a smoking cessation aid?
- The Agency could take (and has taken) enforcement action against manufacturers that makes unsubstantiated drug claims (*e.g.*, that e-cigarettes could help someone quit smoking)

E-Cigarettes as Drug Products

- The scientific and medical communities have determined that nicotine is a pharmacological agent, that nicotine addiction is a disease, and that nicotine withdrawal is itself a recognized medical condition
- Marketing an e-cigarette as a smoking cessation aid involves a claim that the product is intended to affect the structure or function of the body and to mitigate, treat, or prevent disease

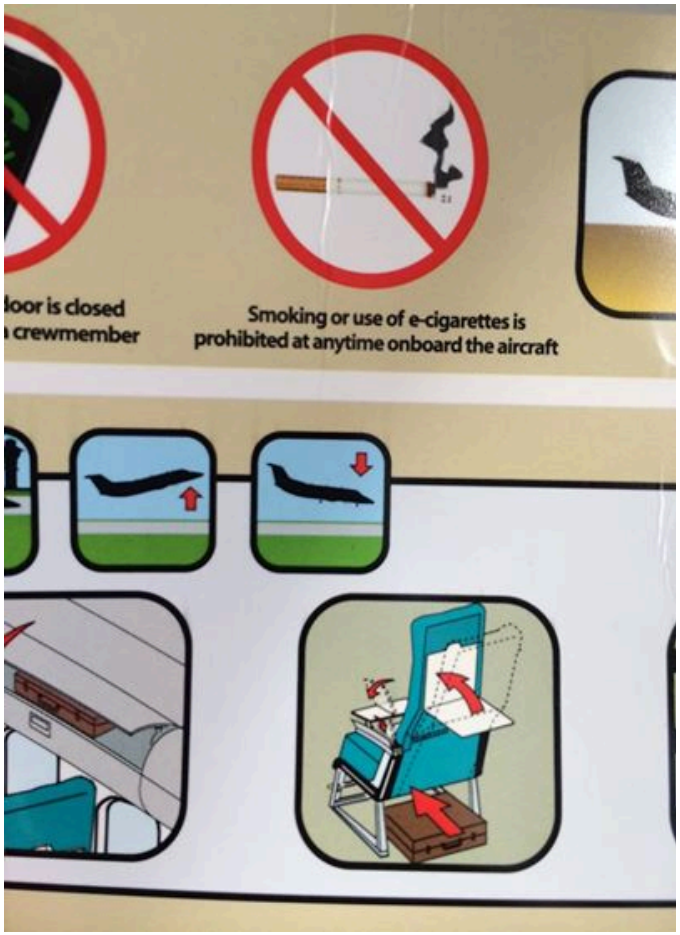
E-Cigarettes as Drug Products

- 21 C.F.R. § 310.544: any product that bears labeling claims that it "helps stop or reduce the cigarette urge," "helps stop or reduce smoking," or similar claims is a smoking deterrent drug product
- Products that are labeled, represented, or promoted as smoking deterrents are regarded as "new drugs" under 21 U.S.C. § 321(P) because there is a lack of adequate data establishing that they are generally recognized as safe and effective for such use
  - *See, e.g.*, FDA Warning Letters to Ruyan America, Inc., Johnson Creek Enterprises, LLC, Gamucci America, E-CigaretteDirect, LLC, and Cixi E-Cig Technology Inc, Ltd.

Beyond FDA- State Enforcement Action

- 41 states, one territory, and numerous localities have adopted minimum age purchase requirements. Some have adopted indoor e-cigarette use bans
- State attorneys general have taken action against e-cigarette marketing targeting youth and making unsubstantiated heath claims
  - In 2010, former CA Attorney General Jerry Brown reached a settlement with Sottera to end sales and marketing to minors, discontinue sales of flavored cartridges, and stop marketing e-cigarettes as cessation devices unless approved by the FDA

Beyond FDA- State, Locality, and Private Restrictions



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Questions?

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