

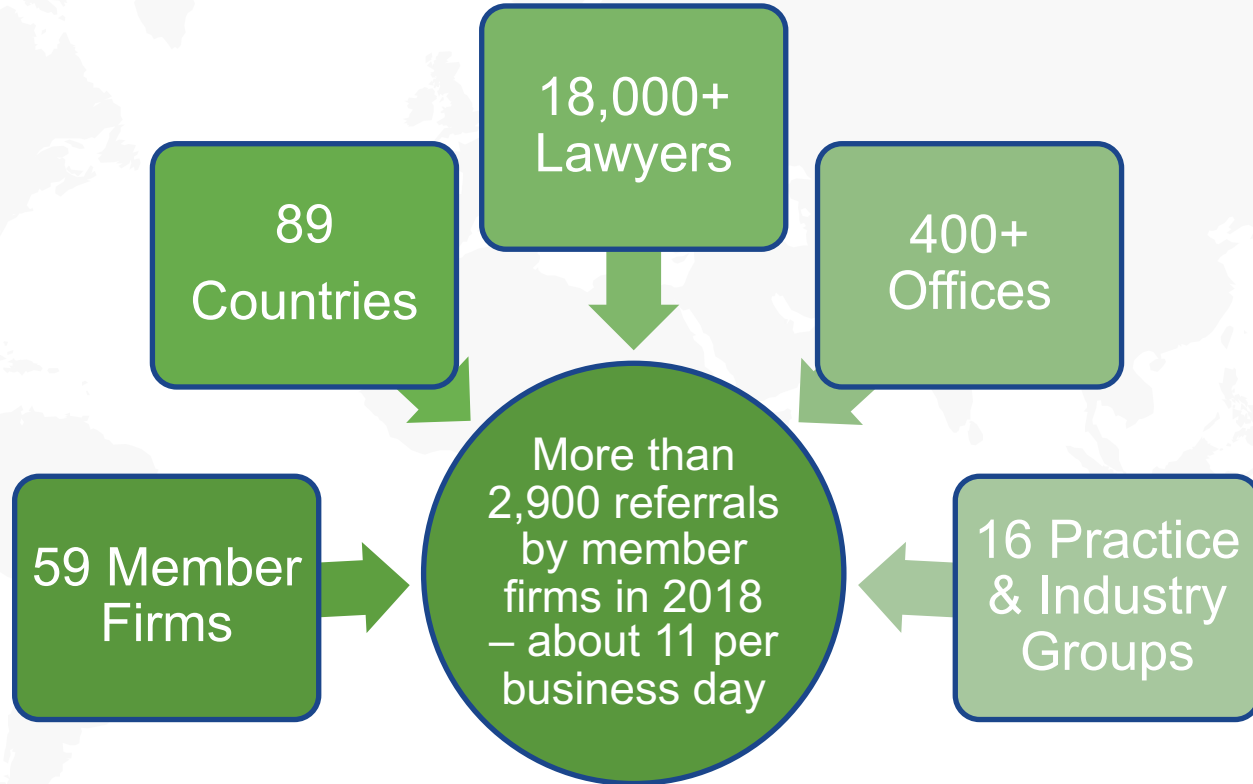


# World Law Group

The Vaping Health Controversy – November 19, 2019



# World Law Group – Quick Facts



# Why World Law Group

- WLG is ranked one of a few “Elite” (Band 1) law firm networks, according to Chambers and Partners
- Qualified, trusted advisors
- Global coverage and local expertise
- Seamless client services
- Established in 1988, our firms have been working together for more than 30 years



# Panelists

- Moderator: Josh Ashby, Lane Powell – Seattle, Washington
- Steven Stein, Greenberg Glusker – Los Angeles, California
- Stephanie Savage, Miller & Martin – Chattanooga, Tennessee
- Pilar French, Lane Powell – Seattle, Washington
- Nikolas Gregor, CMS Germany – Hamburg, Germany



# Vaping - California

- OVERVIEW
  - California health officials have warned against vaping
  - Many California localities have banned vaping
  - California has sued Juul
- MINIMIZING RISK
  - Things to consider for clients in vaping-adjacent spaces



# Differences of Tobacco and Cannabis

- What is Tobacco?
  - Tobacco is the commonly known name of the plant *Nicotiana tabacum* which produces leaves that contain nicotine.
  - Nicotine is an alkaloid, nitrogen-containing chemical, produced synthetically by the tobacco plant.
  - The dried leaves of the tobacco plant are used for smoking , vaping, chewing, etc.



# Differences of Tobacco and Cannabis

- What is Cannabis?
  - The Controlled Substances Act defined “marihuana” as:
    - “all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin” containing greater than .3 % delta-9 THC on a dry weight basis, and except that marijuana does not include the stalk and fiber produced from such stalks.
  - Many states have legalized the recreational and medicinal use of marijuana.
  - The dried flower of the plant is used for recreational and medicinal smoking, vaping, and other consumer product purposes.



# Delivery Systems

- Vaporizers, E-Cigarettes and other Electronic Nicotine Delivery Systems:
  - Also called vapes, e-hookahs, vape pen, etc., are devices that heat a liquid solution to create an aerosol that users then inhale into their lung.
  - The liquid solution may contain any number of ingredients. The main constituents are propylene glycol, with or without glycerol, and flavoring ingredient.
  - Depending on whether the solution is manufactured for tobacco or cannabis purposes, the solution may also contain nicotine, tetrahydrocannabinol (THC) and cannabinoid (CBD) oils, and other substances and additives.





# Differences in Cannabis Products

- The use of Vitamin E in Cannabis Vapes
  - The CDC has identified vitamin E acetate as a chemical of concern among people with e-cigarette, or vaping, product use associated lung injury (EVALI).
- Why?
  - Vitamin E may be used as an additive in THC-containing e-cigarette, or vaping, products because it acts as a thickening agent to THC.
- The Risk
  - Vitamin E usually does not cause harm to ingest orally as a supplement or apply transdermally to the skin, however when inhaled, research suggests that Vitamin E may interfere with normal lung functioning.
- Product Manufacturing Source
  - Consumers are obtaining products from unreliable sources and substance are being added to the solutions to modify its use.



# Some states have restricted or banned vape products

State	Restrictions
<b>California</b>	In San Francisco, e-cigarettes may not be sold within the city. Effective October 1, LA County banned flavored tobacco. California has launched an ad campaign against vaping, underage sales and counterfeit products.
<b>Delaware</b>	Law makers are considering banning flavored vape products and restricting advertising.
<b>Illinois</b>	HB 3887 is pending to ban Flavored e-cigarettes and tobacco products.
<b>Iowa</b>	No ban. Focusing on education. State has concluded that 34 of 43 reports are associated with illegal street market cartridges.
<b>Massachusetts</b>	4 month ban on all vaping products effective Sept 24 through Jan 25, 2020, although a court ordered an exception for flower vaping devices.
<b>Michigan</b>	Effective September 4, 2019, sweet, mint and menthol flavor were banned but the ban has been blocked by court order.
<b>Montana</b>	Adopted a ban but a court blocked it.



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<b>Montana</b>	Adopted a ban but a court blocked it.
<b>New Jersey</b>	A bill to ban flavored e-cigarettes will be presented in 2020.
<b>New York</b>	Adopted a ban but it has been blocked in litigation
<b>Oregon</b>	Adopted a 180 day ban but a court orders have blocked the bans.
<b>Rhode Island</b>	Effective October 4, flavored vaping products banned; unflavored tobacco products not banned.
<b>Washington</b>	On September 27, Washington adopted a ban concerning flavored vaping products. Governor wants the legislature to ban tobacco products as well. A trade organization has filed suit to block the ban. Trial court denied a request for a temporary injunction.
<b>Utah</b>	On October 3, Utah saw to ban sales of flavored cigarettes. Litigation is pending



# Arguments Presented to Block Various Bans

- Bans on all products are unconstitutional, overly broad, and arbitrary and capricious.
  - Studies show that vaping products are safer than combustible cigarettes
  - Evidence shows that THC products predominately caused the lung injury outbreak.
  - Bans should be narrowly tailored
    - to avoid financial devastation to the industry.
    - Other laws may be in effect to protect marketing to youths.
  - Bans might violate commercial speech.

*See, e.g., Petition for Declaratory and Injunctive Relief, Vapor Technology Association et al. v. State of Washington Board of Health et. al., Thurston County Superior Court No. 19-2-06196-34.*



# Litigation Filed by Government Entities

- States, cities, counties, DA, and even school districts are suing
  - These cases claim improper marketing to youths while failing to disclose addictive or dangerous nature of the product.
  - Theories of recovery:
    - Racketeering
    - Unlawful and Deceptive Trade Practices
    - Public Nuisance
    - Fraud



# ***Breja v. Juul et al., Whistleblower Litigation***

- Recently, a disgruntled employee has filed suit against Juul claiming that he was wrongfully terminated after attempting to stop Juul from selling contaminated mint flavored nicotine pods.
- Defending against that case will be important because plaintiff's attorneys may use that complaint in furtherance of other lawsuits filed by consumers or governmental agencies.



# Proactive Solutions

The industry is already taking a positive approach. . .

- Proactive litigation is very important to curb knee jerk reactions from holders of political offices.
  - Injunction litigation filed by trade organizations can promote education and make sure that regulations are properly tailored.



# Proactive Solutions

- Crisis management and PR experts are important.
  - Pushing a message for science based regulation is key.
  - Messaging about the positive effects of vaping is also important.
  - But because the industry has been exposed to a “frenzy”; repeating this message over and over will be important.





# Proactive Solutions

- Good corporate citizens want to work with governments.
  - Emphasize scientific support and positive impacts on health, as well as impact that overly rigorous reactions can have on the economy.
  - Maintain strong internal controls relating to product safety and advertizing.
    - Set the standard.
    - Juul settlement committing not to marketing to youths.



# Proactive Solutions

- Work with state attorneys general and the FTC/FDA to tailor sales to promote health and safety.
  - We note that just today the Trump administration is delaying on any specific ban.
- States and federal governments have recently experienced local governments push for monetary recoveries (opioid litigation; banking litigation). This has put these various governmental agencies at odds and raises constitutional issues.
- Vaping companies that can reach cooperative arrangements with state or federal agencies may be able to stave off local lawsuits, and save litigation costs.



# The Vaping Health Issue in Europe

- News reporting about the US cases and controversy
- However, no reports about similar cases occurring in Europe
- Reasons:
  - Vaping yet less popular
  - THC/CBD consumption through vaping yet less common
  - Stricter regulations?
  - No functioning reporting system?
  - Luck?

*“We have not seen anything like what we’ve seen in the U.S. recently in Europe, to my knowledge as a scientist, and I’m pretty aware of the field.”*

Constantine Vardavas, European Respiratory Society



# The Regulatory Framework in the EU

- **Article 20** EU Directive 2014/40/EU on tobacco and related products + national laws
- Most important rules:
  - Bureaucratic notification requirement 6 months prior placing on the market, comprising e.g. name and contact details, list of ingredients and emissions (incl. quantities), toxicological data, nicotine doses and uptake etc.
  - Strict rules on permissible ingredients (max. volume of 2ml/10ml for refill containers; max. nicotine: 20mg/ml; prohibition of certain additives (vitamins, stimulant compounds like caffeine, colouring additives, additives facilitating inhalation or nicotine uptake; additives with CMR properties in unburnt form etc.)
  - Specific surveillance obligations
  - Reporting obligations
  - Strict rules for labelling and advertising



# The Regulatory Framework in the EU

- However, **TPD does not apply to cannabis vaping**:
  - Definition of e-cigarette: "a product that can be used for consumption of nicotine-containing vapour via a mouth piece, ..."
- Vaporizers used with CBD/THC liquids only fall under Product Safety Directive and the resp. national laws
  - Products must be safe
  - Manufacturers must inform consumers of any risks associated with the products
  - Manufacturers must make sure any dangerous products present on the market can be traced so they can be removed to avoid any risks to consumers
  - CE marking



# Contact Info

- Joshua Ashby, Lane Powell – Seattle, Washington
  - [AshbyJ@lanepowell.com](mailto:AshbyJ@lanepowell.com)
- Steven Stein, Greenberg Glusker – Los Angeles, California
  - [stein@greenbergglusker.com](mailto:stein@greenbergglusker.com)
- Stephanie Savage, Miller & Martin – Chattanooga, Tennessee
  - [Stephanie.Savage@millermartin.com](mailto:Stephanie.Savage@millermartin.com)
- Pilar French, Lane Powell – Seattle, Washington
  - [FrenchP@lanepowell.com](mailto:FrenchP@lanepowell.com)
- Nikolas Gregor, CMS Germany – Hamburg, Germany
  - [Nikolas.Gregor@cms-hs.com](mailto:Nikolas.Gregor@cms-hs.com)

