

GTNF FIELD TRIP 2014

Evolution of the e-Vapor Industry: Past, Present and What the Future Holds

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Preliminary Word

- This presentation provides information about the law. Legal information is not the same as legal advice, which involves the application of law to an individual's specific circumstances. The interpretation and application of the law to an individual's specific circumstance depends on many factors. This presentation is not intended to provide legal advice.
- The information provided in this presentation is drawn entirely from public information. The views expressed in this presentation are the authors' alone and not those of the authors' clients.

Presenters

- **John Bellinger** is the inventor of the wattage-controlled personal vaporizer and co-owner of Evolv. Mr. Bellinger has several personal vaporizer and e-cigarette patents pending. He holds a degree in mechanical engineering from Carnegie Mellon University in Pittsburg, Pennsylvania, USA.
- **Brandon Ward** is the founder and co-owner of Evolv Inc. Mr. Ward has over 20 years of senior executive level experience in the private sector.
- **Azim Chowdhury** practices in the area of food, drug and tobacco law, with a focus on electronic cigarette products. Mr. Chowdhury advises corporations in matters of FDA and international regulatory compliance.

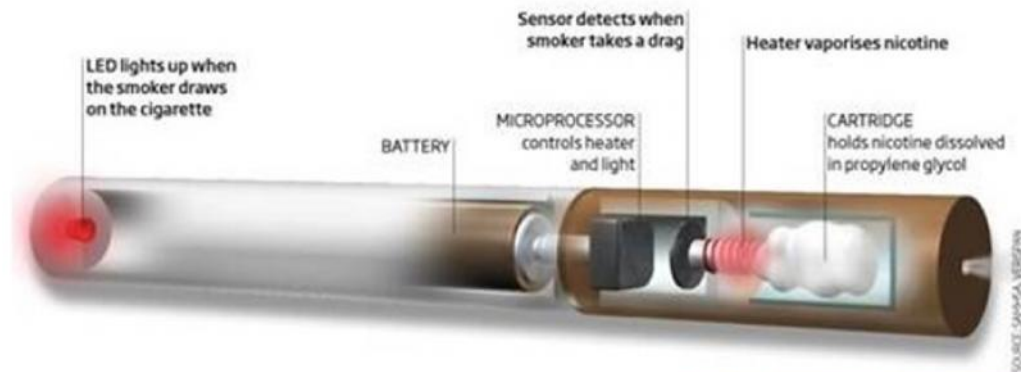
Agenda

- Evolution of E-Cigarette Technology
 - *From Cigalikes to APVs*
- Evolution of E-Cigarette Regulation
 - *Where we are now*
 - *Impact of FDA's Deeming Regulation*
- What the Future Holds
 - *Where Technology is Headed*
 - *Alternative Regulatory Frameworks*
- Questions & Answers

Evolution of E-Cigarette Technology

What is an E-Cigarette?

- “Cigalike” – designed to mimic the look and feel of a conventional cigarette



Evolution of E-Cigarette Technology

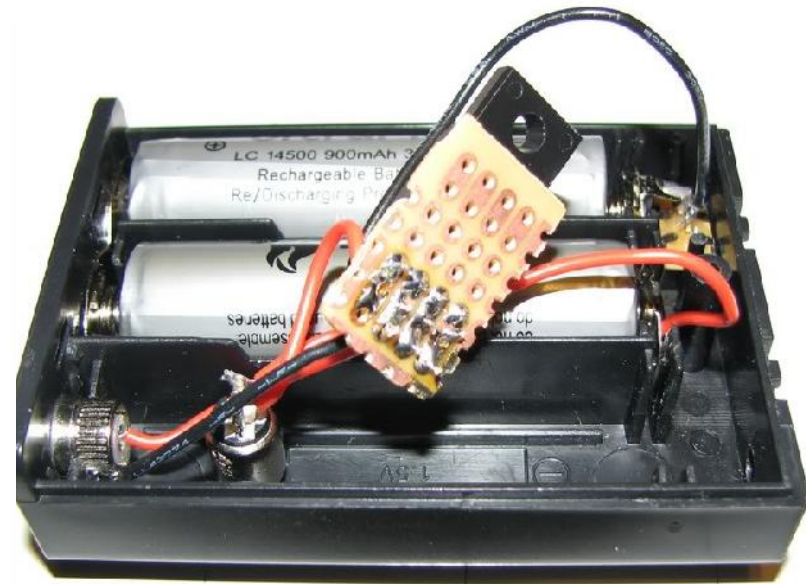
Cigalikes are a Transitional Technology



Evolution of E-Cigarette Technology

Devices (2008-2009)

Original Advanced Personal Vaporizers (APVs)



Evolution of E-Cigarette Technology

- Early APV's
 - Were created to more accurately simulate smoking
 - More powerful
 - Longer battery life
 - Hobbyist built devices
 - Referred to as 'mods'
 - Typically a repurposed commercial product or assembled from easily obtainable parts
 - Social media communities formed to share open source APV designs (ECF)

Evolution of E-Cigarette Technology

Devices (2010)

APV's



**Fixed voltage
and removable
battery**

Evolution of E-Cigarette Technology

- APV's (2010)
 - The Joye Ego is released (closed system)
 - eGo was the first commercially available regulated APV
 - Several unregulated 'big battery mods' were commercially released
 - Variable voltage introduced but not widely available

Evolution of E-Cigarette Technology

Devices (2011)

APV's



**Variable Voltage and
Variable Wattage**

Evolution of E-Cigarette Technology

- APV's (2011)
 - Variable voltage devices become commercially available
 - Evolv releases the Darwin, the first power regulated (variable wattage) device is released
 - Open system eGo's become available

Evolution of E-Cigarette Technology

Devices (2012 to present)

APV's



itazte
SVD^{NA}_{2.0}

EVOLV



Evolution of E-Cigarette Technology

- APV's (2012 to present)
 - Many new manufacturers enter the industry
 - Power regulated (variable wattage) and Variable voltage devices dominate the market
 - The Variable voltage/ wattage eGo was introduced
 - In 2014 VW devices have become the market standard
 - Proliferation of the local vape shop has introduced APV's to wider consumer base

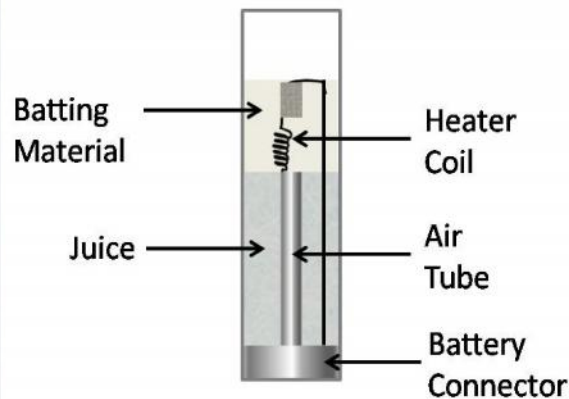
Evolution of E-Cigarette Technology

Consumables- An evolution in taste and capacity

- Original APV consumables



Cartomizer



Atomizer

Evolution of E-Cigarette Technology

- Cartomizers
 - Held less than a ml of juice, needed refilled often
 - Needed replaced after a day or two
 - Muted flavor due to batting material
- Atomizers
 - Used primarily for dripping
 - Better flavor but inconvenient

Evolution of E-Cigarette Technology

Consumables- An evolution in taste and capacity

- First Tank system



Evolution of E-Cigarette Technology

- Early tank systems
 - Invented by a truck driver
 - Required the user to punch holes into a cartomizer
 - Prone to leakage
 - Suffered from the same problems as the cartomizer
 - Cartomizer manufacturers eventually offered pre-punched cartomizers

Evolution of E-Cigarette Technology

Consumables- An evolution in taste and capacity

- Modern consumables



Evolution of E-Cigarette Technology

- Modern consumables
 - Based on the original tank system
 - Easy to use
 - Not prone to leakage
 - No batting, better flavor
 - Hold more e-juice
 - Replaceable coils
 - Available in many colors and form factors

Evolution of E-Cigarette Regulation in the United States

Electronic Cigarettes: Are they subject to FDA Regulation?

- The first cigalike products started being sold in the United States around 2007-2008.
- In 2008, FDA initially attempted to ban certain cigalikes and their components from being imported into the country from China, claiming these products were unapproved “drug delivery devices.”
 - Drugs and medical devices cannot be marketed unless they have received FDA premarket approval by demonstrating that they are safe and effective for a therapeutic use.
- FDA added e-cigarettes and their components to Import Alert 66-41, preventing importation.

Electronic Cigarettes: Are they subject to FDA Regulation?

- After their shipments were seized on import, the plaintiff e-cigarette companies filed a lawsuit in 2009, arguing that they were not drug delivery devices, but tobacco products under the **Family Smoking Prevention and Tobacco Control Act**, which had just become effective in June 2009.

Electronic Cigarettes: Are they subject to FDA Regulation?

- The Tobacco Control Act amended the Federal Food, Drug and Cosmetic Act to give FDA the authority to regulate the manufacture, distribution, and marketing of tobacco products to protect public health.
 - See *FDA v. Brown & Williamson*
- The Tobacco Control Act broadly defines a “tobacco product” as anything made or derived from tobacco intended for human consumption, including any component, part or accessory of a tobacco product. **But...**

Electronic Cigarettes: Are they subject to FDA Regulation?

- The Tobacco Control Act only gave FDA immediate authority to regulate certain types of tobacco products:
 - Cigarettes
 - Cigarette tobacco
 - Smokeless tobacco
 - Roll-your-own tobacco
- Not included: other tobacco products, such as e-cigarettes, cigars, pipe tobacco, and dissolvable tobacco
 - These products will be captured by the proposed “Deeming Regulation”. **How?**

Electronic Cigarettes: Are they subject to FDA Regulation?

- In addition to the enumerated product types, the Tobacco Control Act applies “to any other **tobacco products** that the [FDA] by regulation deems subject to [the law].”
- Why are e-cigarettes **tobacco products**, and not “**drug delivery devices**,” since they do not contain tobacco, and are used to deliver nicotine into the body?
- Remember tobacco product **definition**: If your nicotine is derived from tobacco, then your e-cigarette is a tobacco product. If not, then it is not subject to FDA’s *tobacco* authority.

Electronic Cigarettes: Are they subject to FDA Regulation?

- D.C. District Court Judge Richard Leon agreed with the Plaintiffs that the products did not fit the definition of a drug; FDA appealed.
- In December 2010, the D.C. Circuit Court of Appeals agreed with the e-cigarette companies and held that so long as the **nicotine is derived from tobacco** and the products are “customarily marketed” (*i.e.*, for recreational use), they are tobacco products, and not drugs. See *Sottera, Inc. v. FDA*.
- In other words, e-cigarettes cannot be marketed as providing any therapeutic benefit, such as a nicotine replacement therapy (NRT) or a quit smoking aid.
- But, although they are tobacco products, they are not *regulated* tobacco products, until FDA *deems* them to be so by way of a regulation.

Electronic Cigarettes: Are they subject to FDA Regulation?

- On April 25, 2011, FDA published a letter on its website to e-cigarette stakeholders conceding that e-cigs are tobacco products and would be captured by the Deeming Regulation. It further stated that e-cigs would be subject to general controls, such as:
 - Registration
 - Product Listing
 - Ingredient Listing
 - Good Manufacturing Requirements
 - User fees for certain products
 - Adulteration/Misbranding provisions
 - **Premarket Review Requirements**

Public Health Standard

- Under the Tobacco Control Act, new tobacco products must be **“appropriate for the protection of the public health”**
 - Different from “safe and effective” standard for drugs and medical devices
 - Recreational use tobacco products are not “safe and effective” for any therapeutic purpose, as tobacco is inherently unsafe.
- This standard requires FDA to assess a new tobacco product’s impact on the public health:
 - Must consider both users and non-users (especially adolescents)
 - Impact on initiation and cessation rates

Electronic Cigarettes: Are they subject to FDA Regulation?

- The Notice of Proposed Rulemaking for FDA’s “Deeming Regulation” was finally published on April 25, 2014.
- The 105-day comment period ended on August 8, 2014. FDA has received over 80,000 comments.
- Once FDA has reviewed all the comments it will prepare a final rule which, once completed, will again be submitted to the White House Office of Management and Budget (OMB) for approval. Final rule must include analysis of the comments.
- If OMB approves, the final rule will become effective and will be published in the Federal Register and eventually in the Code of Federal Regulations (21 CFR).
 - The entire “Notice and Comment Rulemaking” process will likely take at least **1-2 years**.
 - Before any major federal rule goes into effect, agencies are required to forward the rule to Congress for review. See *Small Business Regulatory Enforcement Fairness Act 1996*.

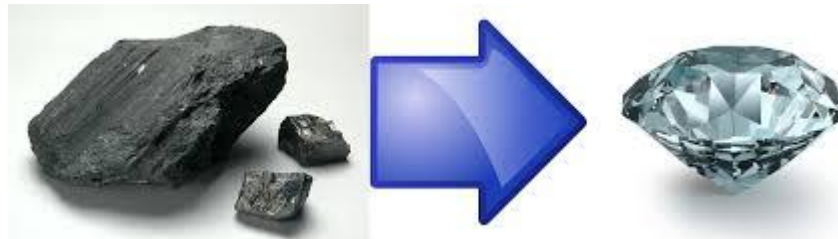
Impact of Deeming Regulation

- If the proposed rule becomes effective as drafted, e-cigarettes will be subject to the same regulatory requirements that currently only apply to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.
- These requirements include registration, product listing, ingredient listing, warnings, restrictions on sales to minors and, most importantly, premarket review.
- Do alternative regulatory frameworks make more sense?

Why FDA is Right to be Concerned

Why FDA is Right to be Concerned

- Compounds plus temperature, pressure and time equals chemical products.



- Until we control the entire process, we can't say with certainty what is in the vapor our users are inhaling.

Why the FDA is Right to be Concerned

- E-cigs and even the best present-day APVs have uncontrolled processes.
- Liquid components can be anything, with no mandatory standards for components or manufacturing process
- Heating process may be completely unregulated

Making a Safer E-Cigarette

- What would a truly safer e-cig be like?
 - All compounds in the fluids have a predictable safety profile.
 - Dosing is reliable and repeatable
 - The only compounds in the vapor are the compounds in the fluid
 - No chemical degradation
 - No interactions between components
 - No burning

Making a Safer E-Cigarette

- Control over heater temperature has been the missing piece.
- Evolv recently began shipping new control electronics that can directly limit the temperature of the heating element. (patent pending)
- The fluid can never get hotter than the heater coil.

Making a Safer E-Cigarette

- Glycerin decomposes to acrolein at 536°F
- Cotton smokes at 401°F



- All organic compounds have a max temperature

Making a Safer E-Cigarette

- Every E-cigarette has only three critical parts
 - Fluid
 - Heating element
 - Control electronics
- Everything else is irrelevant if basic consumer product safety standards are followed.

Alternative Regulatory Frameworks

Alternative Regulatory Frameworks

- Nicotine-only products vs. tobacco leaf-containing products
- Continuum of Risk
 - The more harmful/riskier the product, the higher the regulatory burden should be
- New “Grandfather Date” –
 - February 15, 2007 vs. Effective Date of Rule?
- Evidence that e-cigarettes are “appropriate for the protection of the public health”
- Use of Product Standards

Alternative Regulatory Framework

- The first and most important part of an FDA standard for e-cigarettes should be a statutory maximum temperature for any portion of the heater or device. We suggest 450 degrees Fahrenheit, but are open to other numbers.
- Each critical component should be tested and approved separately. This prevents an unsafe system from being assembled by the end user.

Alternative Regulatory Framework

- Each potential fluid component, whether base liquid, flavoring, nicotine or other shall be tested to not degrade with extended exposure to the regulatory maximum temperature.
- Each potential fluid component shall be tested to not react chemically with all other pre-approved components with extended exposure to the regulatory maximum temperature.

Alternative Regulatory Framework

- Each potential fluid component shall be tested to not react chemically with any approved heater or cartridge material.
- If all these conditions are met, then any finished e-liquid product made from approved components will have the same predictable safety profile as the components, and therefore does not require explicit testing or approval.

Alternative Regulatory Framework

- Heating elements and fluid holding containers must be made only of approved, non-reactive materials and must not degrade when exposed to the regulatory maximum temperature for an extended period of time.
- Heating elements must be tested with compatible, pre-approved control electronics to demonstrate effective temperature limiting.

Alternative Regulatory Framework

- Control electronics must prevent the heating element from exceeding the regulatory maximum temperature regardless of user input.
- Should multiple standards exist to limit the temperature, the control electronics or devices must not connect to or not heat incompatible heating elements.

Alternative Regulatory Framework

- With a regulatory temperature limit, there is no reason to approve each specific combination of device, fluids, heating elements and control electronics. Any combination of approved components will be equivalent.
- Without a temperature limit, even exhaustive testing and pre-market approval cannot guarantee a product with a predictable safety profile.

E-Cigarettes to Advanced Personal Vaporizers

Why are consumers transitioning?

Growing Market

- The U.S. e-cigarette market has seen rapid growth over the last 5 years, with sales of \$2 to \$3 Billion expected in 2014 (including both cigalike and APVs).
- While some analysts have predicted e-cigarette sales to surpass conventional cigarettes in 10 years, recent reports have indicated a decline in sales, at least with respect to cigalikes.
- But market for APVs is continuing to grow – why?

Evolution of E-Cigarette Technology

Cigalikes are a Transitional Technology

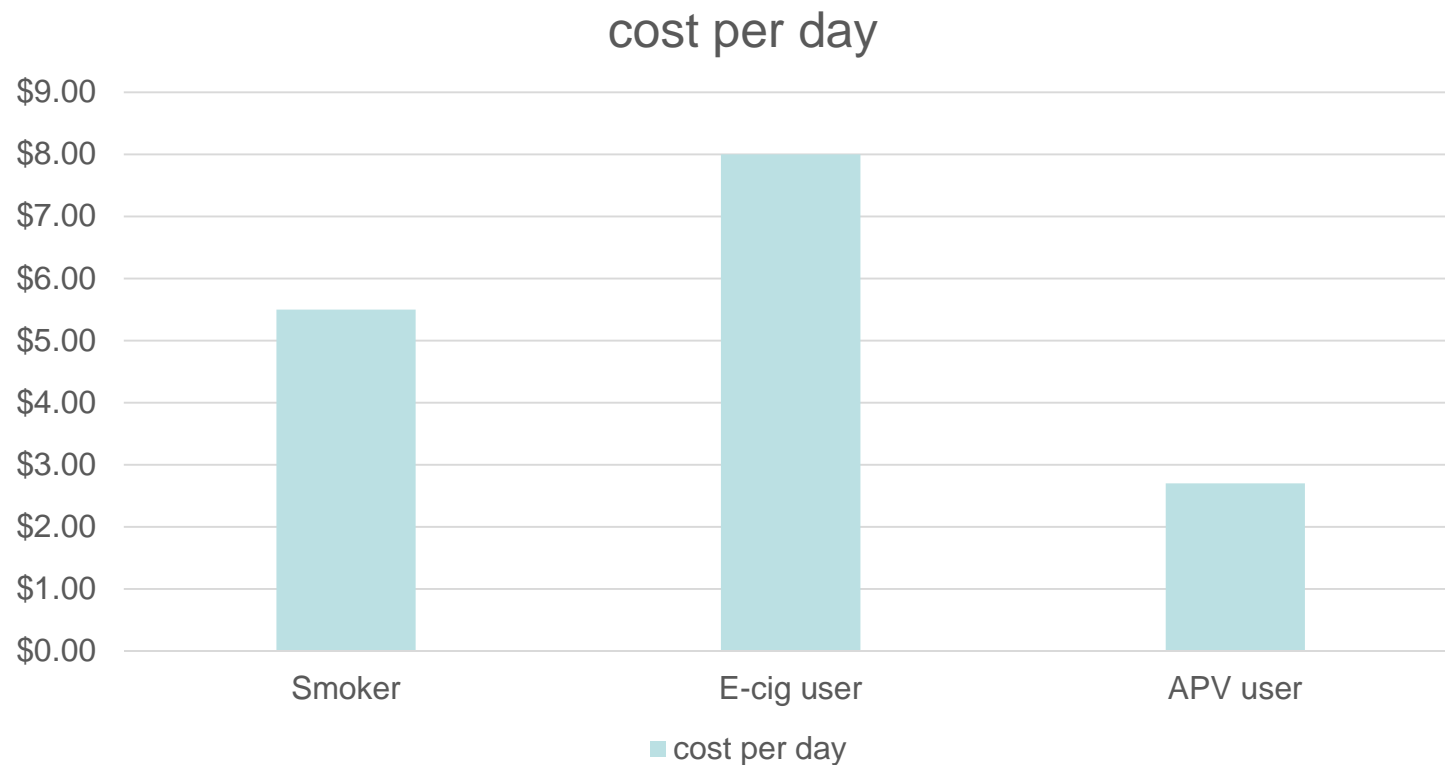


Evolution of E-Cigarette Technology

- An APV does not resemble a cigarette
 - Social Stigma associated with smoking
- An APV has a larger battery
 - Longer use time between charges
- An APV typically employs a variable regulated output
 - More accurately simulates a cigarette
 - More consistent
- An APV has a standard connector which accepts consumables from different manufacturers
 - The open system allows more choice and personalization
- All APV's are refillable

Evolution of E-Cigarette Technology

- Being an APV vaper is less expensive than smoking; significant potential for uncaptured revenue



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Thank you!

Any questions?

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