

Nicotine without smoke

Electronic Cigarettes

- ✓ Nicotine
- ✗ No Ashes
- ✗ No Butts
- ✗ No Fire Hazard
- ✗ No Smoke – Just Vapor
- ✗ No Lingering Bad Odor



Nothing is burned, so there are no ashes, no butts to dispose of and no second-hand smoke. The vapor dissipates quickly and has no lingering odor. No study has found harmful levels of any chemical or carcinogen in e-cigarette vapor.

How effective are they?

The success rate for complete replacement of smoking ranges from 31% to 79% according to three published surveys.

What are the health effects?

In multiple surveys, over 90% of users report that their health has improved since they completely or even partially switched from inhaling smoke to inhaling vapor. The most frequently reported health improvement is in lung function, with coughing and wheezing reduced or eliminated.

Research

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CASAA Lab Reports Collection:

http://casaa.org/Lab_Reports_ecigarettes.html

CASAA

Electronic Cigarettes (E-Cigarettes): The Facts



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What is an e-cigarette?

An electronic cigarette (e-cigarette) consists of a battery; an atomizer; and a cartridge that contains propylene glycol (PG) or vegetable glycerin (VG), water, flavoring, and optional strengths of nicotine. When the user activates the unit, the battery supplies heat to the atomizer, which vaporizes some of the liquid in the cartridge.

Is there more than one type?

Some models resemble a real cigarette, a real cigar, or a real pipe. Many are odd shapes and cannot be mistaken for the real thing. Some models have a button that must be depressed when inhaling to activate the vaporization. These models are called "manual." Some models combine the atomizer and cartridge into a single piece, called a "cartomizer."

Are there other names for it?

"Electronic cigarette" is often shortened to e-cigarette or e-cig. Another name for this type of product is Personal Vaporizer (PV).

Are they a smoking cessation product?

No. FDA-approved "smoking cessation" products are intended to be used as treatment for nicotine addiction. E-cigarettes are intended to be used as a replacement for smoking tobacco cigarettes, supplying a less harmful source of nicotine.

Are they safe?

While nothing is ever 100% "safe," due to the fact that nothing is burned, e-cigarettes don't deliver the things that cause smoking-related disease and death. Vapor contains no tar, no carbon monoxide, no particulates, and none of the thousands of chemicals that are created by combustion. Nicotine does not cause lung disease, heart disease, or cancer. Reports of *minor* adverse health effects appear to be far more rare than more serious reports involving FDA-approved pharmaceutical nicotine products.

What about the FDA's tests?

The FDA's press release of July 2009 left out important information. A day's supply of liquid contains no more nitrosamines ("carcinogens") than FDA-approved nicotine products. (See box at right.) The quantity of diethylene glycol detected in the liquid was well below toxic levels and has never been detected in the vapor. In short, the FDA did not find harmful quantities of any substance.

Who uses them?

The Etter & Bullen survey found that 99.7% were current daily, occasional, or former smokers; and 70.2% no longer smoke. (See links on back panel.)

Why are flavors offered?

Most consumers start out wanting a unit that looks like and vapor that tastes like their brand of cigarette. As they move away from smoking tobacco cigarettes, they begin to find the tobacco flavors distasteful. Over 80% of 2,168 survey respondents said they have used non-tobacco flavored liquid, with 51.9% using fruit or candy flavors on a regular basis.

Nanograms of Tobacco-Specific Nitrosamines in a one-day supply of products containing nicotine:

Quantity	Product	Ng.
1 gram	16 mg. e-cigarette liquid	8
1 each	21 mg. nicotine patch	8
10 pieces	4 mg. nicotine gum	20
1 pack	Marlboro full-flavor cigarettes	126,000



AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION

Creating responsible and sustainable practices
and process for the safe manufacturing of
"e-liquids" used in electronic cigarettes.

Version 1.7 | 12.6.2012



E-LIQUID MANUFACTURING STANDARDS

RESPONSIBILITY • STANDARDS • TRANSPARENCY



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Purpose

The purpose of these Standards is to create a responsible and sustainable practices and process for the safe manufacturing of “e-liquids” used in electronic cigarettes. Our members believe we have a responsibility to self-regulate the e-liquid manufacturing process based on professional criteria. AEMSA aims to accomplish this by creating, implementing and upholding standards for the manufacture of e-liquids. One of AEMSA’s primary goals is to provide consumers with higher degrees of confidence our members’ products are manufactured with professionalism, accuracy and safety

AEMSA standards are established based on the following Core Beliefs:

- We have a responsibility to verify the accuracy of any nicotine content in the products we distribute.
- We have a responsibility to ensure the quality and safety of all ingredients in our e-liquids.
- We have a responsibility to prepare our products in a clean, sanitary and safe environment.
- We have a responsibility to ensure our products are packaged and delivered in a safe manner.
- We have a responsibility to provide a level of transparency into the monitoring and verification process.

The 2012 AEMSA Standards are living documents and subject to changes according to the AEMSA corporate structure and procedures.

Scope

These standards apply to all AEMSA general members that engage in the manufacturing or processing of E-liquids. 2012 E-Liquid Manufacturing Standard will be used as a basis for:

- Evaluating compliance for membership acceptance
- Confirming compliance of existing membership



Definitions

Term	Definition
Active Age Verification	Taking active measures to ensure that all customers are of legal age. Can be accomplished in many ways including Photo Identification and 3rd party verification systems. Note: Having pop up box asking the person to indicate they are over a specified age is not Active Age Verification
ASTM - American Society for Testing and Materials	An international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services
Chain of custody	The chronological documentation or, showing the custody, control, transfer, analysis, and disposition of physical component; tracking a product along the supply chain to the point of sale
Components	A part or element of a larger whole; a substance that forms part of a mixture. Any substance, material or the tangible substance that goes into the manufacturing of e-liquid
Contaminants	An impurity or foreign substance present in a material or environment that affects one or more properties of the material
Custard Notes	Flavor compounds that impart a buttery, creamy, or custard taste or sensation. Most commonly used are acetoin, acetyl propionate and diacetyl
Dedicated Manufacturing Space	A clean safe environment that is used exclusively for the manufacturing of e-liquid
Diacetyl	A natural byproduct of fermentation. It is a vicinal diketone (two C=O groups, side-by-side) with the molecular formula C ₄ H ₆ O ₂ . Diacetyl occurs naturally in alcoholic beverages and is added to some foods to impart a buttery flavor. It has been eliminated from many commercial flavorings due to risk of lung damage
Direct Operation	A facility or process where Full time employees for an organization directly supervise and oversee production and process
DIY	Do it Yourself
Electronic cigarette	Also known as an e-cigarette (e-cig) is an electrical inhaler that vaporizes a propylene glycol and/or glycerin-based liquid solution into an aerosol mist simulating the act of tobacco smoking
E-liquid	Liquid for producing vapor in electronic cigarettes, known as e-juice or e-liquid
E-liquid manufacturing	Fabrication: the act of making something (a product) from raw materials; to include all processes from supply acceptance to the point of customer delivery
Free-base	An amine or nitrogen-containing organic compound, such as nicotine, in its basic (high pH) form, in contrast to its acidic (low pH) form, which is often called the "salt" form. Unless an acid has been added to nicotine, or it is purchased as the salt, it is in the free-base form. Free-base describes the form of the compound, not its purity
Generally Recognized as Safe (GRaS)	Generally recognized as safe (GRAS) is an American Food and Drug Administration (FDA) designation that a chemical or substance added to food is considered safe by experts, and so is exempted from the usual Federal Food, Drug, and Cosmetic Act (FFDCA) food additive tolerance requirements
Indirect Operation	A facility or process where supervision and/or oversight of production and/or process for an organization is conducted by a 3rd party or contractor (subcontractor)



Mg / ml	Milligrams per Milliliter – a scale (or ratio) for measuring an ingredient component, in liquid form, where accuracy is measured in mg per ml - or a percentage equivalent
Nicotine	Nicotine is an alkaloid found in the nightshade family of plants (Solanaceae) that acts as a nicotinic acetylcholine agonist. The biosynthesis takes place in the roots and accumulation occurs in the leaves of the Solanaceae. It constitutes approximately 0.6–3.0% of the dry weight of tobacco and is present in the range of 2–7 µg/kg of various edible plants
NIST -The National Institute of Standards and Technology	A non-regulatory agency of the United States Department of Commerce. The institute's official mission is to: Promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life
OSHA	The United States Occupational Safety and Health Administration (OSHA) is an agency of the United States Department of Labor. Congress established the agency under the Occupational Safety and Health Act, was signed into law on December 29, 1970. OSHA's mission is to "assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance"[2]. The agency is also charged with enforcing a variety of whistleblower statutes and regulations
PPM	Parts Per Million
SINGLE-USE ARTICLES	Utensils, containers and tools designed and constructed to be used once and discarded
Tamper Evident	Tamper-evident describes a device or process that makes unauthorized access to the protected object easily detected. Seals, markings or other techniques may be tamper indicating
Titration	Also known as titrimetry, is a common laboratory method of quantitative chemical analysis that is used to determine the concentration of an identified component; the determination of rank or concentration of a solution with respect to water with a pH of 7 (the pH of pure H ₂ O under standard conditions)
USP (US Pharmacopoeia)	The United States Pharmacopeia (USP) is the official pharmacopeia of the United States, published dually with the National Formulary as the USP-NF. The United States Pharmacopeial Convention (usually also called the USP) is the nonprofit organization that owns the trademark and copyright to the USP-NF and publishes it every year. Prescription and over-the-counter medicines and other health care products sold in the United States are required to follow the standards in the USP-NF. USP also sets standards for food ingredients and dietary supplements
WTA (whole tobacco alkaloids)	A full-spectrum mixture of all alkaloids extracted from whole tobacco. WTA can contain, in addition to nicotine, anabasine, cotinine, myosmine, anatabine, and/or nornicotine, in varying compositions, largely dependent on the tobacco species



E-Liquid Manufacturing Standard

Article I. Verifying the accuracy of the nicotine content in products

Section 1.01 Accuracy of nicotine

- (a) All manufactures must confirm the accuracy of nicotine content upon delivery from supplier

Section 1.02 Titrated/verified after dilution

- (a) All nicotine must be titrated/verified for content accuracy after dilution to working level

Section 1.03 Measuring nicotine equipment

- (a) All equipment used in measuring nicotine from working level to final product must be either
 - (i) NIST (calibrated)
 - (ii) ASTM compliant (calibrated)

Section 1.04 Tolerance level

- (a) All products produced will be within the tolerance level of +/-5% nicotine content in final product

Section 1.05 Maximum allowable nicotine content

- (a) The maximum allowable nicotine content in final flavored product will be no greater than 36 mg / ml

Section 1.06 Retail nicotine sold for unflavored/DIY nicotine

- (a) Will follow the same criteria for verifying the nicotine content and quality on all batches when received and titrated after dilution at various sales levels
- (b) Is not subject to maximum allowable nicotine content in final flavored product

Article II. Ensure the quality and safety of the all ingredients of in e-liquid

Section 2.01 Nicotine Sources

- (a) All manufacturers must purchase and comply with at least one of the following:
 - (i) USP CERTIFIED nicotine (with evidentiary documentation from a certified lab)
 - (ii) Free-base nicotine from suppliers who can provide source evidentiary documentation from a certified lab confirming (batched) nicotine conforms to the Nicotine Quality Standard (see Section 2.02)
 - (iii) Purchase from nicotine suppliers who can provide evidentiary documentation from a certified lab confirming the incoming (batched) free-base nicotine conforms to the Nicotine Quality Standard (see Section 2.02)

Section 2.02 Nicotine Quality Standard

- (a) All nicotine used in manufacturing must meet the following nicotine quality standards:
 - (i) Nicotine purity greater than or equal to 99.0% *
 - (ii) Total combined of all other possible contaminants less than or equal to 1.0%
 - (iii) Per existence of any solvent must not exceed 0.06%
 - (iv) Per existence nicotine oxide less than or equal to 1%
 - (v) Per existence nicotine-N-oxides less than or equal to 1%
 - (vi) Cumulative heavy metals *content* cannot exceed 10ppm
 - (vii) Cumulative Arsenic *content* cannot exceed 1ppm
 - (viii) All diluents after source pure must be USP certified thru chain of custody

Section 2.03 Base liquid ingredients

- (a) Base liquid diluent ingredients such as Propylene Glycol, Vegetable Glycerin, Glycerol, or any other e-liquid bases (either regularly or exclusively) will be at a minimum level of USP (US Pharmacopoeia) grade certified



- (i) Material must maintain full certification throughout chain of custody on raw materials used in manufacturing process
- (ii) Manufacturer must exclusively use certified base products throughout the manufacturing process

Section 2.04 Ingredients/ Components other than base liquids

- (a) Ingredients/ Components other than base liquids will contain only safe or highest grade base materials
 - (i) Flavorings (including menthol) used will be at a minimum of food grade and/or Generally Recognized as Safe (GRAS) standard certifications whenever the ingredient is produced at those standards
 - (ii) Flavorings containing artificial food coloring will identify food coloring information to include coloring number in advertising and product descriptions
 - (iii) Flavorings containing Custard Notes will identify advertising and product descriptions
 - (iv) Water used (if any) will be either deionized or distilled
 - (v) Alcohol and additional additives (if any) will be:
 - 1) Used in the purest form commercially available and safe for human consumption
 - 2) Minimum of US Food grade standards

Section 2.05 The following will not be added or used in the creation of e-liquids

- (a) Including but not limited to:
 - (i) Diacetyl
 - (ii) WTA (whole tobacco alkaloids)
 - (iii) Medicinal - or prescription medicinal
 - (iv) Illegal or controlled substances
 - (v) Caffeine
 - (vi) Vitamins or Dietary supplements (other than for preservative purposes)
 - (vii) Artificial Food Coloring
 - 1) AEMSA members will not add any artificial coloring or dyes during the e-liquid manufacturing process. Non vendor manufactured flavorings containing artificial food coloring will identify food coloring information to include coloring number in advertising and product descriptions
 - (viii) AEMSA reserves the right to review, evaluate and deny/approve any potential substance used in the creation of e-liquids at any given time

Section 2.06 Process/Records/Traceability

- (a) Manufacturers will maintain sufficient process and records to enable the manufacturer to trace any individual product distributed to the test results for nicotine content to include source nicotine (see section 2.02)

Article III. Clean, Sanitary and Safe Preparation of Products

Section 3.01 General

- (a) All Lab/Mixing employees are required to be fully familiar with all AEMSA standards
 - (i) There will be a special emphasis placed on nicotine handling, storage and clean-up
- (b) Each member will create and maintain written lab/mixing protocol and make accessible to all lab/mixing employees
- (c) All Persons allowed in process area must comply with applicable protection/ safety and standards
- (d) All products will be created and/or bottled in dedicated manufacturing space reserved exclusively for e-liquid

Section 3.02 Manufacturing Environment

- (a) Manufacturing processes will meet food preparation standards to include
 - (i) Non-porous sanitized preparation work surface



- (b) All surfaces in lab/mixing area (floors, counters, etc.) shall be cleaned with anti-bacterial agents at least once each day and after any spill of any mixing ingredient or any possible-contaminants
- (c) Equipment will be cleaned by FDA Approved Chemical Sanitation or autoclave
- (d) All supplies and material will be disposed of in a manner that is appropriate to component disposal - proper disposal of production material
- (e) There shall be no open fans, dusty boxes and/or other potential sources of airborne contaminants etc. in dedicated space
- (f) All bottles and materials unpacked outside of dedicated lab/mixing space

Section 3.03 Hand washing / sanitation

- (a) Not in sink used for cleaning mixing utensils, and/or other e-liquid materials
- (b) Minimum 20 seconds with commercial (food handler's grade) antibacterial hand washing agent and warm water
- (c) Hands washed each and every time entering mixing room
- (d) After bathroom use, coughing, sneezing, eating and/or drinking, engaging in any other activities which potentially expose hands to any form of potential contaminants
- (e) During mixing as often as necessary to remove any mixing products on hands
- (f) Before proceeding to a subsequent mixing session -> to prevent any cross contamination from one batch to the next

Section 3.04 Health / illness

- (a) All open wounds or abrasion will be properly covered
- (b) Any/All mixing employees report any illness/abrasion(s)/lesions to person in charge before entering the process
- (c) Employees must report to person in charge if exposed to any contagion or infection - viral or bacterial - from anywhere (including others in their homes, other work environments, other domiciles, etc.) before entering lab/mixing area
 - (i) Such exposure/conditions excludes said individual from entering mixing room for a period of three (3) asymptomatic days have passed and/or cleared with medical documentation (equivalent to commercial food handling)
 - (ii) Discharge from eyes, nose and/or mouth:
 - (iii) Report to business any persistent discharge from eyes, nose, and/or mouth. Any employee exhibiting such symptoms shall not enter the mixing room until such symptoms cease

Section 3.05 Eating/Drinking

- (a) No eating, drinking, vaping and/or smoking in the lab/mixing area at any time

Section 3.06 Hair Restraints

- (a) Each member must establish written hair and beard standards

Section 3.07 Animals

- (a) No animals shall be permitted in the mixing room at any time for any reason

Section 3.08 POISONOUS OR TOXIC MATERIALS

- (a) POISONOUS OR TOXIC MATERIALS shall be stored so they cannot contaminate PRODUCT COMPONENT, FOOD, EQUIPMENT, UTENSILS, and SINGLE-USE ARTICLES by:
 - (i) Separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning
 - (ii) Locating the POISONOUS OR TOXIC MATERIALS in an area that is not above PRODUCT COMPONENTS, FOOD, EQUIPMENT, UTENSILS, or SINGLE-USE ARTICLES
 - (iii) This does not apply to EQUIPMENT and UTENSIL cleaners and SANITIZERS that are stored in WAREWASHING areas for availability and convenience if the materials are stored to prevent contamination of PRODUCT COMPONENT, FOOD,



EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES

- (iv) All POISONOUS OR TOXIC MATERIALS will be disposed of in a safe manner
- (v) Only those POISONOUS OR TOXIC MATERIALS that are required for the operation and maintenance of a lab/mixing area, such as for the cleaning and SANITIZING of EQUIPMENT and UTENSILS and the control of insects and rodents, shall be allowed in a lab/mixing area (kept sealed and separate - never above - from any/all mixing supplies)
- (vi) A container previously used to store POISONOUS OR TOXIC MATERIALS may not be used to store, transport, or dispense any other substance

Section 3.09 Employee Safety

- (a) Employers MUST provide their employees with a workplace that does not have serious hazards and follow all relevant OSHA safety and health standards including - but not limited to - the following mandatory personal protective equipment (P.P.E.):
 - (i) Eye protection
 - (ii) Lab Coat / Apron
 - (iii) Fully covered footwear
 - (iv) All manufacturing spaces must have easily accessible
 - 1) First aid kit
 - 2) Emergency eye wash kit

Article IV. Safe Packaging and delivery of products

Section 4.01 Child proof caps

- (a) Child proof caps required for all consumer level e-liquid products
- (b) Zero Nicotine Products do not require child proof caps

Section 4.02 Tamper evident packaging

- (a) All Products require tamper evident packaging once leaving vendor chain of custody

Section 4.03 Labeling

- (a) Smear Resistant Labeling is required on all e-liquid products
 - (i) Must pass "30 second submerged" test for all required elements
- (b) Nicotine content must be clearly displayed
- (c) Safety and health Warning must be clearly displayed
 - (i) Contains Nicotine
 - (ii) Keep away from Children and Pets
- (d) Nicotine Traceability elements (i.e. Batch ID or nicotine batch ID or production date)

Section 4.04 Delivery

- (a) All shipped liquid must be bagged or wrapped to provide waterproof barrier between packaging and product for spill protection
- (b) Safe handling information must be included in all packaging

Section 4.05 Active age verification

- (a) All Vendors must use Active age verification for all sales (retail and/or online) (
- b) AMESA Members will not knowingly sell products to any persons under the legal smoking age

Article V. Transparency into the monitoring and verification process



Section 5.01 Within the organization

- (a) Members must provide information to applications and compliance committees required to establish compliance including:
 - (i) Documented evidence of compliance
 - 1) Photographic and Video evidence
 - 2) Unfettered access to facilities for inspection (scheduled and/or unscheduled)
 - 3) Process and records
- (b) Member to member profiles will contain only minimal information for the identification and communication amongst and between members
 - (i) Current status of compliance - by facility
 - (ii) Contact Information
 - 1) Name
 - 2) DBA
 - 3) Email
 - 4) Phone
 - 5) Location(s)/ Facilities of production

Section 5.02 To the consumer

Note: Subsections (a) and (b) are already posted on AEMSA website. **Subsections (c) and (d) are intended for specific information warranted situations ONLY; these may include - but not limited to - allergy sensitivities, other specific medical conditions/sensitivities, etc.** Subsection (e) shall be available on member's web site

- (a) A substantive version of the AEMSA Standards be published on Website
- (b) AEMSA Membership Status
- (c) **Members will provide consumers tracking nicotine test results as far back as the source nicotine**
 - (i) **Information on the supplier may be redacted to protect intellectual property and trade secrets**
 - (ii) **The member may charge a reasonable and fair fee for said tracing requests**
- (d) **Members will provide answers to consumers on ingredients of products**
 - (i) **Yes/No answers to specific questions as pertains to specific customer sensitivity questions**
 - (ii) **No intellectual property or trade secrets of the e-liquid ingredient has to be revealed**
 - 1) **This includes revealing the source supplier and trademarked/brand name ingredient**
- (e) Clearly identified products that are not manufactured by AEMSA Members
 - 1) If the member sells liquid that is manufactured in a non AEMSA compliant facility it must:
 - 2) Clearly identify/ differentiate products that are AEMSA compliant and those that are not AEMSA compliant on a product by product basis

Section 5.03 To potential regulators

- (a) To be decided on case by case basis

Why AEMSA?



WE STRONGLY BELIEVE AEMSA IS THE MOST TIMELY, POSITIVE, CONSTRUCTIVE AND PROACTIVE WAY TO CREATE A VOICE WHERE NO OTHER OPPORTUNITIES TO BE HEARD EXIST

Current estimates indicate numbers exceeding Five Million people worldwide are using electronic cigarettes as an alternative to combusting and smoking tobacco. The popularity and use of electronic cigarettes is growing daily all around the world. Vaping is a relatively new smoking alternative that made its primary debut into the USA approximately six years ago and has grown exponentially in popularity.

Electronic cigarettes, e-liquids and vaping are currently not regulated by any governmental authority. The U.S. Court of Appeals, District of Columbia, upheld a lower court decision deeming the FDA can regulate electronic cigarettes as tobacco products. To date, the FDA has not regulated electronic cigarettes or the manufacturing of e-liquids vaporized while using

electronic cigarettes. While AEMSA acknowledges liquid nicotine is derived from tobacco, we do not agree that it is a tobacco product.

As a newer technology and smoking alternative, various scientific testing of the ingredients, health implications and possible impacts in the direction of second hand vapor have begun([links](#)). We are all enthusiastic about the early indications from the results of testing completed and in progress. More testing is needed and AEMSA supports informative testing to effectively and accurately analyze any/all potential health implications of this newer alternative. AEMSA believes the primary focal point of potential regulation needs to be on the e-liquids themselves. After all, it is the e-liquids that are being vaporized, inhaled and exhaled.

There has been much discussion and speculation surrounding possible regulation of electronic cigarettes and e-liquid. This category of products is comparatively new to the world AND the regulatory environment. Technologies and consumable products have never before been combined and utilized in this fashion. Nobody anticipated such profound permeation of the smoking populace, the rate of development of these products and especially the profound life altering improvements many vapers have been experiencing in their quality of life after adopting this **Tobacco Harm Reduction** smoking alternative.

Vaping has grown at such an unprecedented rate that a global sub-culture and community of vaping enthusiasts has developed and will continue to grow at an impressive rate. Clearly, so many – as evidenced by the exponential growth rate – are embracing this new alternative. So many have stopped smoking altogether and made a complete switch to using electronic cigarettes. Consequently, the demand for these products is also climbing at an unanticipated scale. Such profound demand seeks supply and there is no shortage of those willing to pursue the economic opportunities.

While so many are enthralled by the growth and popularity of this **Tobacco Harm Reduction** smoking alternative, it has clearly been seen that some form of regulation is both inevitable and necessary. However, the simple identification of this necessity does not help create the needed regulation. We strongly believe AEMSA is the most timely, positive, constructive and proactive way to create a voice where no other opportunities to be heard exist.

AEMSA believes e-liquid, as an entirely new consumable product category, requires a new approach to regulation. AEMSA acknowledges the reality that governmental regulation is most likely on the immediate horizon and advocates for reasonable and practical regulation.

We also appreciate the reality that the legislative process can, and probably will, be arduous and lengthy. We have seen fear based efforts to ban electronic cigarettes and vaping in various municipalities around the world. We have also seen those attempting these bans self-admitting they lack sufficient information and are therefore acting from fear and ignorance. While we do not agree with such actions, we acknowledge these are sometimes promulgated with protective intent. However, even though possibly well intended, such actions can take away an obviously popular Tobacco Harm Reduction smoking alternative that seems to be having profoundly positive impacts on millions of lives around the world.

The Charter Members of AEMSA decided to create an organization to facilitate, develop and self-regulate standards designed to

provide consumers with much higher degrees of confidence in the manufacturing processes of these products. AEMSA advocates the responsible and professional approach to the manufacturing process and hopes to contribute to, and assist with, the actual regulatory formation of reasonable, effective and sustainable regulations for the manufacture and distribution of American made e-liquids in the marketplace.

The American E-liquid Manufacturing Standards Association has been created, in both form and function, to accommodate any and all American e-liquid manufacturers who choose to participate while meeting and maintaining all AEMSA standards. This structure is designed to facilitate collaboration, growth, creativity and to influence reasonable, practical and effective regulation for the manufacture and sale of electronic cigarette e-liquids. We have established an application and review process along with a full structure for various committees, evaluations, reviews, amendments, and more. Members agree to both scheduled and unscheduled inspections.

AEMSA is currently is a 501c(6) non-profit entity.

AEMSA welcomes and encourages all American e-liquid manufacturers to apply, join and **have a VOICE** in the growth and development of this unique trade association.

Welcome to AEMSA

Welcome to AEMSA.ORG, the first and only Manufacturers' trade association completely dedicated to creating responsible and sustainable standards for the safe manufacturing of "e-liquids" used in electronic cigarettes. AEMSA is an all-volunteer organization, formed by American manufacturers of e-liquids, to promote safety and responsibility through self-regulation. **[Read More]**

"As a community, and an emerging industry we have a choice, to stand by and watch disinformation and fear continuously be disseminated to the public at large, or we can come together and create a structure to educate, inform and facilitate."

-Linc Williams, We Are Vapers

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Archive

February 2014

ECBlend - Certification, FDA cGMP, Better Business Bureau, OSHA, Environment



July 2013 **ECBlend** is pleased to announce its successful certification by the American E-Liquid Manufacturing Standards Association (Aemsa.org)

ECBlend's certification by AEMSA will give customers added confidence that our products are verifiably manufactured in a clean, sanitary, and safe environment. And that ECBlend uses ingredients that meet or exceed the standards set by an association of our peers in the pursuit of verifiable Quality, Safety and Accuracy.

The E-Liquid industry is growing, and ECBlend leadership is required to take this certification program to the next level. Focus, commitment, and an understanding of the industry are imperative. ECBlend includes certification as a component of our business package; our belief in the importance and benefits of certification are evident. Our Certification by Aemsa is a natural fit for ECBlend, and we are confident that we are continuing to fulfill our commitment to our customers and our responsibilities to the industry and consumers.



AEMSA and Transparency: It is not good enough to just "PASS" the Certification. Aemsa Certified Members must maintain their certification status: Aemsa guidelines include the requirement that all Certified Members maintain transparency in its processes. Aemsa Certified Members agree to surprise inspections at any time of its facilities, processes & procedures, and its products.

AEMSA Standards Purpose [[Aemsa.org Purpose](http://Aemsa.org/Purpose)]

"The purpose of these Standards is to create a responsible and sustainable practices and process for the safe manufacturing of e-liquids used in electronic cigarettes. "

"One of AEMSA's primary goals is to provide consumers with higher degrees of confidence our members' products are manufactured with professionalism, accuracy and safety."



Aemsa and the FDA



July 26, 2013

In March 2013, and again in July 2013, Aemsa represented its membership in 'listening' sessions with the FDA.

AEMSA: "During the first 'Listening Session' (March 21, 2013), we introduced the FDA to AEMSA's Structure, Membership, Mission, Standards, Science behind the Standards (SME presentations), how the Standards are applied by our General Members in their facilities and our Inspections (both scheduled and unscheduled). Clearly, by the very nature of AEMSA, these were all directly in relation to Re-Fillable E-liquids and the manufacturing processes."

AEMSA returned in July 2013 and presented on how these Re-Fillable E-Liquids are used by consumers: *Aemsa:* "the AEMSA team brought a representative collection of sample hardware products (examples of the most common spectrum). We presented on the evolution, application(s) and contributions these products make towards efficacy. Product samples were made available for FDA representatives to see in both sealed packaging (as sold) and open for hands-on direct viewing. We believe that for the FDA to understand these products, they needed to see and learn about them with direct and actual physical interaction."

ECBlend and the Better Business Bureau

ECBlend Flavors announces its commitment to marketplace ethics by earning Accreditation with Better Business Bureau. As a BBB Accredited Business, ECBlend has met BBB's Code of Business Practices and has agreed to maintain honest and reliable business practices.

BBB's Accreditation Program recognizes dependable businesses that are making the public pledge to: Be transparent, be responsive to customers, advertise honestly, honor promises, and act with integrity.

ECBlend's Accreditation includes our local stores as well as our online services.

ECBlend, OSHA and Employee Safety - ECBlend has invited OSHA to our facilities twice. This Aemsa Certification is yet another milestone for ECBlend Flavors and in conjunction, we value the safety of our employees and the contributions of OSHA regulations to their well-being.

Employing over 90 employees in our manufacturing facility in Medford, Oregon, USA, ECBlend strongly believes the safety of our Employees is paramount. ECBlend products will not be produced in an unsafe environment for our employees.

ECBlend complies with OSHA including maintaining a management OSHA rep and employee OSHA reps and the appropriate committee. ECBlend Employee OSHA reps are empowered to ensure the safety of our staff.

ECBlend - Nicotine and the Environment - ECBlend has taken steps to ENSURE the safety of our environment and the proper disposal of nicotine waste. We have worked with City of Medford Public Works - RWRF to ensure we are following all proper disposal regulations, rules, and requests by them.

ECBlend and FDA cGMP (current Good Manufacturing Practice) in Manufacturing, Packaging, and Labeling of E-Liquid Products



Although E-Liquid Manufacturing is currently unregulated by the FDA, ECBlend voluntarily follows Current Good Manufacturing Practice for food manufacturing. In a discussion between the FDA and an ECBlend representative in mid-2012, the FDA stated they could not recommend specifically which product to follow. E-Liquid is unique and because it contains nicotine would not fall under cGMP for Food nor was it regulated by the FDA's Center for Tobacco Products (CTP) at that time. (As of this writing, the FDA intends to regulate e-cigarettes as tobacco products.)

Our product labeling complies with FDA labeling laws. ECBlend polybags every bottle before shipping to ensure the safety of the delivering carrier and the tamper evidence requirements.

ECBlend Processes and Improvements

ECBlend is a leader in its industry with continuous and sustainable growth. Our management team has achieved this by reviewing our processes, then implementing improvements and revisions on a continuing basis. We continually evaluate modern processes and equipment, we actively seek outside expertise when needed and we seek to join, collaborate and work with our industry associations and support groups.

**ECBlend strives to provide the best products at reasonable prices for its customers.
ECBlend is .. something better®**

Was this article helpful? [yes](#) / [no](#)

Article details

Article ID: 63
Category: [About ECBlend](#)
Rating (Votes): ☆☆☆☆☆ (68)

What's in E-Liquids?

ECBlend uses only FDA approved and pharmaceutical grade ingredients in our E-Liquid products. (Note we are referring to our ingredients. The FDA intends to regulate e-cigarettes under tobacco laws. (Public Statement, FDA))

Our flavorings are completely natural wherever possible. (Some flavors are artificially flavored, just like food flavorings and are safe to vape.) Our flavorings do not use Diethylene Glycol in any of our E-Liquid products.

ECBlend uses only 100% USP Food Grade Kosher Propylene Glycol (PG) and Vegetable Glycerin (VG). (There are no animal by-products in either our PG or VG.)

[Sources: http://en.wikipedia.org/wiki/Electronic_cigarette#Liquids ECBlend.com]

[CLICK HERE FOR an INGREDIENTS LIST](#)

Liquids used to produce vapor in electronic cigarettes are widely sold both as separate bottled products, for use with refillable cartridges, and as pre-filled disposable cartridges. **Bottled liquid is sold under a variety of names, including "e-liquid", "e-juice", and "nicotine solution".**

Contents of liquid solutions vary, but their common aspects include (distilled) water and flavorings in a propylene glycol (and/or) glycerin base. Nicotine is also included in solutions intended to fulfill a nicotine replacement role. (source:http://en.wikipedia.org/wiki/Electronic_cigarette#Liquids This statement has not been evaluated by the FDA)

Flavors

ECBlend uses only water-soluble flavorings. We do not use essential oils in any of our e-liquids.

ECBlend has over 250 flavors available. Our categories include Drink flavors, Sweets and Desserts, Tobacco, Fruits, and Flavorless. Popular flavors include Chocolate Hazelnut Tobacco, Ruyan 4, Red Box, 7 Leaf Tobacco, Apple, Strawberry, Watermelon, Dragon Fruit, Chocolate Covered Toffee and Cherries, Coffee Your Way, plus our popular Create Your Own Wizard allowing you to mix and match up to 4 flavors in any percent you want.

All Natural & Organic flavoring ingredients in 100% VG Base

FLAVORINGS These water-soluble recipe flavorings are Certified Organic, All-Natural, Kosher, Vegan, Gluten Free, and contain No Allergens. These flavors have no nutritional value as used in this application are calorie, carb, and sugar free. There is no fat. Enjoy.

Flavoring Ingredients: Organic and Natural Flavors, Vegetable Glycerin, and Natural & Organic Ethyl Alcohol* (Ethyl Alcohol is a base in the flavoring, it is not an additive by ECBlend*) There is no sugar in these e-liquids.

*ETHYL ALCOHOL FDA PART 184 – DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE Subpart B—Listing of Specific Substances Affirmed as GRAS Sec. 184.1293 Ethyl alcohol. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=184.1293>

100% VG Base: ECBlend uses Pure 100% USP Food Grade Kosher Vegetable Glycerin (VG). (There are no animal by-products in either our PG or VG.)

There are no e-liquids that taste like a traditional tobacco cigarette. In a traditional tobacco cigarette you are tasting the combustion (burning) of the tobacco. The flavor of tobacco e-liquids is the true actual flavor of the tobacco, not the burning of it.

Nicotine

Liquid solutions containing nicotine are available in differing nicotine concentrations to suit user preference. Dosing nomenclatures are not standardized and vary by manufacturer, but tend towards the following rough figures:

- Liquids said to contain "low" doses of nicotine tend to correspond to a nicotine concentration of 6–8 mg/ml (milligrams of nicotine per milliter of liquid).
- "Midrange" or "medium" doses tend to correspond to a nicotine concentration of 10–14 mg/ml.
- "High" doses tend to correspond to a nicotine concentration of 16–18 mg/ml.
- "Extra-high" doses tend to correspond to a nicotine concentration of 24–36 mg/ml.

Actual numerical nicotine concentration ratings are usually printed on liquid containers or cartridge packaging. Often, the standard notation "mg/ml" is shortened to a simple "mg".

Bases

Flavors and nicotine are dissolved in hygroscopic components, which turn the water in the solution into a smoke-like vapor when heated. Commonly used hygroscopic components include propylene glycol (PG), vegetable glycerin (VG), and

polyethylene glycol 400(PEG 400). **ECBlend uses PG and VG.**

ECBlend does not dilute any of its base liquids with distilled water or ethyl alcohol (Note: ethyl alcohol is included in the ingredients on our e-liquid bottles because it is included in our concentrate flavors by our manufacturers.)

Safety of liquid bases

All three liquid bases are **common food additives used in a variety of pharmaceutical formulations.**

Propylene glycol, the current dominating liquid base, has been utilized in asthma inhalers and nebulizers since the 1950s, and because of its water-retaining properties, is the compound of choice for delivering atomized medication. **The U.S. Food and Drug Administration (FDA) includes propylene glycol on its list of substances Generally Recognized as Safe (GRAS), and it meets the requirements of acceptable compounds within Title 21 of the Code of Federal Regulations.**

ECBlend uses only 100% USP Food Grade Kosher Propylene Glycol (PG) and Vegetable Glycerin (VG). (There are no animal by-products in either our PG or VG.)



Consumer Advocates for Smoke-free Alternatives Association

8 Biggest Electronic Cigarette Myths

There are many myths and misconceptions about electronic cigarettes. Let's separate fact from fiction.

Myth #1 - Electronic cigarettes are a threat to children/teens.

FALSE.

Where it comes from:

Legislators and anti-smoking groups assume that children will be drawn to the “electronic gadgets,” the fruit/candy flavors and ease of access on the internet & mall kiosks.

Why it's a wrong:

First, they aren't easy to purchase on the internet. A credit card or bank account is required. So, unless the child steals a parent's credit card and then hides the card statement later on, the risk of being discovered is high. The majority of kiosk vendors have already implemented a policy of forbidding sales to minors. The opportunity for minors to purchase electronic cigarettes at those kiosks is no better than purchasing tobacco cigarettes at a gas station – probably less.

Second, the least expensive electronic cigarette starter kits run between \$35 - \$50 (plus shipping) online and \$90 - \$150 at mall kiosks. This price point is considerable for the average adult, let alone a child. Children would be more likely to spend that money on music, clothes or video games than an electronic cigarette – especially when they can easily get a \$7 pack of cigarettes at the corner store or from friends. Electronic cigarettes also require the additional purchases of accessories and replacement parts. A single battery costs over \$10. Heating elements, which require frequent replacement, cost over \$8 each.

Third, anecdotal accounts indicate that children/teens view electronic cigarettes as a way for adults to quit smoking. They lack the “danger factor,” which reduces appeal. Additionally, surveys of electronic cigarette owners show that the average consumer is overwhelmingly between 30-50 years old and a smoker¹, indicating that even young adults do not find them particularly appealing.

Myth #2 - Sweet flavors and flashy packaging are intended to specifically attract young people.

FALSE.

Where it comes from:

The assumption by critics that the slick advertisements and fruity flavors only appeal to children and their lack of knowledge of the target consumer and the intended purpose of the product.

Why it's wrong:

These products are not intended to be a treatment for nicotine addiction. They are intended to be a way for current smokers to "smoke" without the dangerous toxins and carcinogens. Retailers need to differentiate themselves from stop-smoking aids, to convince long-time smokers that the electronic cigarette is just as appealing as the tobacco cigarette they currently use.

Just as with marketing cars, televisions, cell phones, alcohol and other adult products, advertisers attempt to make the devices appeal to adults with a "coolness factor." Studies show that "smokers are more likely than the general population to be risk-taking, extroverted, defiant, and impulsive"⁷ - very similar to teen demographics - so the misconception is understandable, but misguided. Often overlooked by critics in these ads are the claims about the ability to "smoke anywhere" and have a safer/healthier option to smoking – a clear indication that they are targeting current smokers and smokers concerned about their health and not new/young smokers.

Regarding sweet flavors, the tobacco-flavored liquid does not have a pleasant taste for many smokers, as it is difficult to replicate the tobacco smoke taste. Adults, who make up the majority of electronic cigarette consumers, specifically requested alternative flavors that would work well with the liquid base – which were mostly sweeter fruit and candy flavors. About 50% of adult electronic cigarette owners polled (over the age of 26)¹ report that they primarily use these non-tobacco flavors and attribute them with the ability to keep them from returning to tobacco cigarettes. They also testify that the sweeter flavors make tobacco cigarettes taste particularly foul and further reduce their chances of returning to smoking cigarettes.

Myth #3 - Electronic Cigarettes all contain anti-freeze.

FALSE.

Where it comes from:

In 2009, the FDA released a press statement claiming that they tested electronic cigarettes and found diethylene glycol, an ingredient in anti freeze.²

Why it's wrong:

Independent labs extensively tested other electronic cigarettes and found no evidence of diethylene glycol, the toxic component of anti-freeze claimed to have been found in the brands the FDA tested.³

To further the confusion, electronic cigarette liquid is made of propylene glycol, an ingredient recognized as safe for human consumption by the FDA. While propylene glycol is sometimes used in anti-freeze, it is an additive intended to make it LESS harmful if accidentally swallowed.

The FDA tested just 18 cartridges, from only two companies. Out of those 18, just one tested positive for "about 1% diethylene glycol."⁴ Because so many other tests failed to find diethylene glycol, many experts conclude that the single sample may have been contaminated in some other way. By no means is it considered a standard ingredient in electronic cigarettes.

If electronic cigarettes did contain anti-freeze, there would be news reports about the thousands of electronic cigarette owners suffering from diethylene glycol poisoning and that is not the case. To date, after five years on the market worldwide, there have been no such reports.

Myth #4 - Electronic cigarettes are just as deadly and carcinogenic as tobacco cigarettes.

FALSE.

Where it comes from:

The FDA stated they found trace amounts of carcinogens in the nicotine cartridges and the media and health organizations used that statement to claim that electronic cigarettes are just as dangerous as tobacco cigarettes.²

Why it's wrong:

The FDA found trace amounts of "tobacco-specific nitrosamines" in the samples they tested, which can cause cancer under certain conditions and in sufficient amounts.⁴ The FDA allows certain levels of nitrosamines in consumable products. For example, tests show that other nicotine products, such as nicotine gum and nicotine patches, also contain the same tobacco-specific nitrosamines. The FDA did not release any information on the levels they found, however, the scientific definition of "trace amount" means amounts that are "detectable," but too small to even accurately measure.

An independent study by Dr. Murray Laugesen showed that, on average, the electronic cigarette contained 8.18ng nitrosamines per 1g of liquid. 8 ng in 1g = eight parts **per trillion**, an extremely tiny amount. By comparison, nicotine gum tested at 2ng, the nicotine patch tested at 8ng and Marlborough cigarettes tested at a staggering 11,190ng. That translates to electronic cigarettes containing 1,200 times LESS of these cancer-causing nitrosamines than tobacco cigarettes and about the same as the FDA-approved nicotine patch.³

Myth #5 - Electronic cigarettes may be more addictive than regular cigarettes.

FALSE.

Where it comes from:

The infamous FDA testing showed that the levels of nicotine found in the cartridges varied from the advertised amount. Also, traces of nicotine were found in cartridges labeled as "no nicotine." Critics claim that means electronic cigarette users may be inhaling too much nicotine and causing them to become even more addicted.

Why it's wrong:

Two independent tests, the one by Dr. Laugesen and one by Dr. Thomas Eissenberg at Virginia Commonwealth University⁵, showed that electronic cigarette vapor does not deliver nicotine as "efficiently" as tobacco smoke and actually delivers nicotine in lower amounts than tobacco smoke.

Additionally, smokers tend to "self-regulate" their intake, as seen by how many cigarettes a smoker uses in a day. When the need for nicotine is met, the smoker – or in this case, the electronic cigarette user – no longer has a craving and ceases consumption. The fundamental behavior of nicotine addiction just doesn't support the claims of increasing the addiction in that manner.

Myth #6 – Second-hand "vapor" is a threat to bystanders.

FALSE.

Where it comes from:

Anti-smoking groups claim the toxins and carcinogens in electronic cigarettes (as well as addictive nicotine) can be accidentally inhaled by bystanders, just like second-hand tobacco smoke.

Why it's wrong:

As shown previously, electronic cigarettes already contain a tiny, barely detectable fraction of the carcinogens found in tobacco cigarettes. They also have been shown not to contain any of the toxins in the amounts found in tobacco cigarettes and that they deliver very little nicotine in the vapor. So, given that the vapor already proves little, if any, danger to the actual user, any danger to bystanders by the exhaled vapor would be negligible.

Additionally, tobacco cigarettes create "side stream smoke," which is the smoke that comes directly from the end of a lit cigarette and the smoke lingers in the air and travels a fair distance from the smoker.

Electronic cigarette vapor does not behave in the same manner as tobacco smoke. There is no vapor produced from the device, until the user activates it by inhaling, so no "side stream vapor" is created and the vapor dissipates very quickly. In the event that a bystander would pass through the vapor, since it doesn't contain the irritating toxins of tobacco smoke, it would likely be barely detectable beyond the faint scent of the flavor and only for a fleeting moment.

Myth #7 - Electronic cigarettes are a "gateway" to tobacco smoking.

FALSE.

Where it comes from:

Critics theorize that more non-smokers will be willing to try electronic cigarettes, due to their attractive flavors and attractive styling.

Why it's wrong:

People start smoking for different reasons. Studies show that children and young adults are more influenced by their peers, parents and stress levels than advertising or flavors.⁶ The most popular tobacco flavors among youth are Camel, Marlborough and Newport – fruit and candy flavors only made up 2% of sales when they were legal – and rarely do people cite the flavor as a reason they started smoking.

Considering that the electronic cigarette is perceived as a health concession for adults, the high start-up costs and the easy accessibility of tobacco cigarettes, electronic cigarettes are unlikely to appeal to new smokers in significant numbers.

Additionally, given the fact that current users claim that electronic cigarettes make tobacco smoke taste considerably foul, in the unlikely event that a new smoker chooses electronic cigarettes over tobacco cigarettes, the chance they will find tobacco smoking appealing is even less.

Taking into account that electronic cigarettes have been shown to be both less toxic and less carcinogenic than tobacco cigarettes, if new smokers actually do choose electronic cigarettes over tobacco cigarettes, it would actually benefit their health and safety and that of those around them.

Myth #8 - If electronic cigarettes were no longer available for smokers, those smokers would simply quit smoking or use traditional stop-smoking aids.

FALSE.

Where it comes from:

Wishful thinking.

Why it's wrong:

According to the 998 poll participants, only 18% responded that they would use traditional NRTs or attempt to quit cold turkey. Nearly 20% said they would switch to other tobacco alternatives, such as snus or snuff; and a whopping 61% indicated they would most likely resume smoking cigarettes.¹

Sources:

1. Consumer Advocates for Smokefree Alternatives, Electronic Cigarette User Poll, CASAA.org
2. US Food & Drug Administration, FDA and Public Health Experts Warn About Electronic Cigarettes, FDA.gov
3. Health New Zealand, Dr. Murray Laugesen, Safety report on the Ruyan e-cigarette Cartridge and inhaled Aerosol, HealthNZ.co.nz
4. US Food & Drug Administration, Final Report on FDA Analyses, FDA.gov
5. Virginia Commonwealth University, Dr. Thomas Eissenberg, Study Reveals a Need to Evaluate and Regulate 'Electronic Cigarettes' "Electronic cigarettes" fail to deliver nicotine , News.vcu.edu
6. Journal of Consulting and Clinical Psychology, Differentiating Stages of Smoking Intensity Among Adolescents: Stage-Specific Psychological and Social Influences, APA.org
7. Dr. Michael Rabinoff, "Ending the Tobacco Holocaust, How Big Tobacco affects our health, pocketbook and political freedom, and what we can do about it." Elite Books, Copyright 2006

CASAA's mission is to ensure the availability of effective, affordable and reduced harm alternatives to smoking by increasing public awareness and education; to encourage the testing and development of products to achieve acceptable safety standards and reasonable regulation; and to promote the benefits of reduced harm alternatives. CASAA is a volunteer, non-profit consumer organization and receives no compensation from any tobacco, pharmaceutical or electronic cigarette companies.

[Back to CASAA.org Main](#)

FRIDAY, AUGUST 9, 2013

New study confirms that chemicals in electronic cigarettes pose minimal health risk

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[UPDATE: The peer-reviewed journal version of this paper is now published: Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. *BMC Public Health* 2014, 14:18 doi:10.1186/1471-2458-14-18]

PHILADELPHIA, Aug. 8, 2013/PRNewswire-USNewswire -- E-cigarette users can breathe a little easier today. A study just released by Professor Igor Burstyn, Drexel University School of Public Health, confirms that chemicals in electronic cigarettes (e-cigarettes) pose no health concern for users or bystanders. This is the first definitive study of e-cigarette chemistry and finds that there are no health concerns based on generally accepted exposure limits.

E-cigarettes are devices that heat a nicotine solution to create an aerosol (called "vapor") that the user inhales, similar to smoking a cigarette. They are used as a low-risk substitute for smoking by millions of former smokers, and their increasing popularity seems to account for the current downward trend in smoking in the U.S. and some other countries. While experts agree that the risks posed by e-cigarettes are significantly less than those posed by smoking, there had been some debate about how much lower the risk was.

By reviewing over 9,000 observations about the chemistry of the vapor and the liquid in e-cigarettes, Dr. Burstyn was able to determine that the levels of contaminants e-cigarette users are exposed to are insignificant, far below levels that would pose any health risk. Additionally, there is no health risk to bystanders. Proposals to ban e-cigarettes in places where smoking is banned have been based on concern there is a potential risk to bystanders, but the study shows there is no concern.

This was the first study funded by the by The Consumer Advocates for Smoke-free Alternatives (CASAA) Research Fund. CASAA, the leading consumer advocacy group promoting the availability and use of low-risk alternatives to smoking, is an all-volunteer, donation-funded organization. CASAA President Elaine Keller said of the study, "Over the years, there have been a lot of small studies of e-cigarette liquid and vapor, but those studies were either ignored or misinterpreted. Those that showed even the slightest contamination were used for propaganda by those who object to e-cigarettes because they look like smoking. We realized that an expert review was needed to give an unbiased explanation of the available scientific evidence for our membership and policy makers. We reached out to our membership and they enthusiastically donated to make it possible."

CASAA Scientific Director, Carl V. Phillips, summarized the importance of the study, saying "It has always been clear that e-cigarettes were much lower risk

than smoking, but there was uncertainty about whether continuing to inhale a mix of chemicals posed a measurable risk. Even those of us who have long encouraged smokers to switch are a bit surprised that even the worst-case-scenario risks are so low. This study assures us that e-cigarettes are as low risk as other smoke-free tobacco and nicotine products, like smokeless tobacco and NRT. All of these products are about 99% less harmful than smoking, and so smokers who switch to them gain basically the same health benefits as if they quit tobacco and nicotine entirely."

Dr. Phillips added that "there has been a call for 'regulatory science' by the FDA. This is exactly the type of science that is needed to make good regulation and informed individual decisions: it summarizes all of the available knowledge and puts the numbers in a useful perspective."

The study did caution that e-cigarette users are inhaling substantial quantities of the main chemicals in e-cigarette liquid (propylene glycol and glycerin). While these chemicals are not considered dangerous and the levels are far below occupational exposure limits, Dr. Burstyn did suggest ongoing monitoring to confirm that there is no risk. The chemical contaminants are of even less concern. While there have been many claims that formaldehyde, acrolein, nitrosamines, metals, and ethylene glycol found in e-cigarette vapor poses a health hazard, the study concluded that all of these have been found only at trivial levels that pose no health concern.

The study did not address the effects of nicotine because e-cigarette users are consuming it intentionally. Nicotine, when it does not involve smoking, is very low risk and has not been clearly shown to cause any disease. However, like caffeine and other common indulgences, it may cause some tiny risk of heart attack and stroke, and so e-cigarettes, along with other tobacco and nicotine products, are probably not risk-free. If there is any risk from nicotine, however, it is so low that it is similar to everyday hazards like drinking coffee or eating dessert, and is far less than the risk from smoking.

The study is available at

<http://publichealth.drexel.edu/SiteData/docs/ms08/f00349264250e603/ms08.pdf>
<http://www.biomedcentral.com/1471-2458/14/18/>

For summary and discussion go to

<http://antithrives.com/2013/08/08/breaking-news-new-study-shows-no-risk-from-e-cigarette-contaminants/>

Contact: Prof. Igor Burstyn igor.burstyn@drexel.edu

Posted by Kristin Noll-Marsh at 4:00 PM



Labels: media, new s

- Given the low risks of e-cigarette use, there is no reason for the State to do anything to make e-cigarettes less accessible to adult consumers who are choosing to use e-cigarettes as a safer alternative to smoking, thereby reducing their health risks by an estimated 99%.
 - The low risk of e-cigarettes is supported by research done by Dr. Siegel of Boston University, Dr. Eissenberg of Virginia Commonwealth, Dr Maciej L Goniewicz of the Roswell Park Cancer Institute, Dr. Laugesen of Health New Zealand, Dr. Igor Burstyn of Drexel University, and by the fact that the FDA testing, in spite of its press statement, failed to find harmful levels of carcinogens or toxic levels of any chemical in the vapor.
 - A comprehensive review conducted by Dr. Igor Burstyn of Drexel University School of Public Health based on over 9,000 observations of e-cigarette liquid and vapor found "no apparent concern" for bystanders exposed to e-cigarette vapor, even under "worst case" assumptions about exposure.
4. Direct them to the CASAA.org website, as well as the CASAA Research Library, for more information.

07:53 AM | 0 Comments

ClearStream LIFE Published



First toxicology study on vapor proves electronic cigarettes are much better than tobacco

Electronic cigarettes have minimal toxicity compared to tobacco, according to the first study of its kind published today online in the journal "Inhalation Toxicology" available [here](#).

The study, called ClearStream-LIFE (clarifying evidence and research on the safety and the risks of electronic atmos), examined the toxic effects of electronic and tobacco cigarettes on cultured living cells. Researchers from Abich toxicological laboratory in Italy and Onassis Cardiac Surgery Center in Greece, led by Dr Giorgio Romagna and Dr Konstantinos Farsalinos, used an electronic cigarette device to produce vapor from 21 commercially-available liquids (Flavourart). The resulting vapor extract was applied to fibroblast cells, which are present in several organs of the human body, including the lungs. During the experiment, one cigarette was smoked and the extract was applied to the same cell type for comparison. The study was performed according to a standardized ISO 10993-5 protocol, with toxicity defined as less than 70% cell survival after 24-hours exposure.

This is the first study that has ever evaluated the toxicity of electronic cigarette vapor. After 24 hours exposure to tobacco smoke from one cigarette, only 5.7% of the cells survived. In comparison, 20 of the electronic cigarette samples were virtually non-toxic (more than 70% survival) and only one sample showed mild cytotoxicity (51% survival). According to the study results, the worst-performing liquid had 795% higher cell survival relative to tobacco smoke. "The results are even more impressive when you consider that we compared one tobacco cigarette with electronic cigarette vapor equivalent to 3 cigarettes", Dr Farsalinos stated.

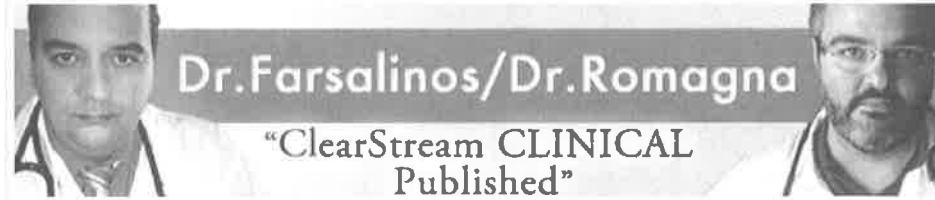
Previous studies have shown that some toxic chemicals may be present in electronic cigarettes, in quantities much lower than in tobacco. Dr Farsalinos commented: "Knowing the chemical composition is important, however evaluating the effects after exposure is even more crucial. The results of this study show that, if present, the amount of dangerous chemicals released from electronic cigarette use is minimal and probably not enough to produce any significant adverse effects on the cells we studied." He added: "In most of the samples tested, cell survival was close to 100%. The quality of electronic cigarette liquids certainly plays a major role in the results. However, until more research is performed and our results are validated by clinical studies we cannot say that they are absolutely safe."

Electronic cigarettes have been marketed in recent years as an alternative-to-smoking habit, and their use is growing exponentially. This has raised concerns among public health authorities in Europe and the US. Dr Farsalinos stated: "Long term studies cannot be performed until 10-15 years have passed. However, research has significantly progressed over the past few years and currently available data indicate that electronic cigarettes are by far less harmful compared to tobacco cigarettes. This is the definition of harm reduction."

Dr Farsalinos continued: "Considering the extreme hazards associated with smoking and that the majority of smokers are unable or unwilling to quit with currently approved methods, there is sufficient evidence to support that switching from tobacco to electronic cigarette use may be beneficial for their health. Public health authorities should make decisions based on scientific evidence."

07:27 AM | 0 Comments

Electronic cigarettes: no adverse effects on blood and oxygen supply to the heart



Electronic cigarette use does not cause any immediate adverse effects on coronary circulation and oxygen supply to the heart, according to a new study presented today in the European Society of Cardiology annual congress in Amsterdam.

Researchers at Onassis Cardiac Surgery Center, lead by principle investigator Dr Konstantinos Farsalinos, evaluated the effects of electronic cigarette use on the maximal ability of the coronary arteries to supply with blood and oxygen the heart itself. They recruited 60 participants, 30 smokers and 30 electronic cigarette users. Measurement of maximal coronary blood flow was performed in smokers before and after smoking 2 cigarettes and, on a separate day, after using an electronic cigarette with 18mg/ml nicotine concentration for 15 minutes. In electronic cigarette users, coronary circulation was evaluated before and after using the same electronic cigarette device for 15 minutes.

"This is the first study that has examined the effects of electronic cigarette use on coronary circulation", said leading researcher Dr Konstantinos Farsalinos. "We know that smoking has immediate adverse effects, lowering the ability of the coronary arteries to deliver blood to the heart, and our purpose was to test whether electronic cigarette use has similar effects", he added.

After smoking 2 cigarettes, the researchers observed a 16% reduction in maximal coronary blood flow and a 19% elevation in resistance to flow. However, after electronic cigarette use, no difference in coronary blood flow and resistance was observed compared to the baseline measurement. "The results are impressive and indicate that, unlike tobacco, electronic cigarette use does not affect the oxygenation of the heart", said Dr Farsalinos. "However, we must be cautious and make clear that this does not mean that there are no implications from long-term use. It is currently impossible to evaluate the effects of long-term use but currently available evidence strongly suggests that electronic cigarettes are by far less harmful alternatives compared to tobacco cigarettes."

Public health authorities all over the world are evaluating the regulatory status of electronic cigarettes. Lately, the European Commission has proposed a medicinal regulation. Dr Farsalinos said: "Acknowledging the significant potential of electronic cigarettes as smoking alternatives and based on the scientific evidence which clearly indicated that they are much safer, it is important that health authorities will regulate these products in a way that will promote rather than restrict their availability and use by smokers who are unable to quit with currently approved medical methods."



I am glad to announce you that on August 26, at 17:15, at the European Congress of cardiology (ESC Congress 2012) in Munich, Dr K. Farsalinos' work on cardiovascular effects of electronic smoke will be presented.

Acute effects of using an electronic nicotine-delivery device (e-cigarette) on myocardial function: comparison with the effects of regular cigarettes (Farsalinos K. et al)

The study, due to its originality and innovation, has been selected for oral presentation in front of 32,000 physicians from all over the world.

Even more importantly for the e-cigarette community, a press conference has been organized by the European Society of Cardiology, presenting this study among the 4 most important smoking-related studies of the congress.

I can not provide you details on the study results, which must remain secret until the date of presentation, but I can tell you that I look forward to personally attend the presentation and gather impressions of colleagues present.

I renew my congratulation to Kostantinos for the excellent work, wishing for him to continue research in this field, always with the same care and originality.

<http://www.escardio.org/about/press/esc-congress-2012/press-conferences/Pages/first-second-hand-smoke-electronic-cigarettes.aspx>

You must be over the age of 18 to purchase or use ECBlend products.

It is our policy and the law in many states and countries. ECBlend believes nicotine products should be regulated from minors:

- Voluntary Compliance: There is no minimum age on this product in Oregon, however, ECBlend voluntarily follows general laws regulating "under 18" products.
- We are an Aemsa Certified member which has certified that we comply with all minimum age requirements. They have examined our materials, website, and procedures.
- On our Warnings (This goes in every package we mail): **You must be over 18 to purchase from ECBlend:** ECBlend's products are intended to be used ONLY by consenting, informed ADULTS OVER THE AGE OF 18 who want to use these products for personal enjoyment. ECBLEND, LLC is located in Medford, OR, USA.
- In our Terms and Conditions: You agree you have read the following warnings and the warnings posted on our website: You must be over 18 to purchase from ECBlend.
- On our business and referral cards: You must be over the legal age in your state or country to buy or use our products.
- During Checkout - before the buyer submits, they must certify they are over 18 and agree to our Terms and Conditions.
- During New Account Setup - the buyer must certify they are over 18 and agree to our Terms and Conditions
- During New Account Setup - the buyer must input their birthdate
- During Setup of a Ship To Address: they must input the birthdate for each address record they set up.
- The message that they must be over 18 is on every material we supply: Business cards, menus, brochures, invoices, packing slips, and on our website in multiple places.
- It is in our terms and agreements, they are required to certify their age during sign up, and then again they must certify their age on every single order they place. They must provide a copy of their ID if ECBlend requests it both online and in-person in our stores.
- In ECBlend Stores: ECBlend follows the federal minimum of carding under 27.
- In ECBlend Stores: Posters: You must be over 18 to purchase these products. We ID under 27.
- In ECBlend Stores: All employees are required to card per the above statements.
- ECBlend wholesalers, resellers and distributors agree not to sell to anyone under 18 or under the legal minimum age for their state or country. They also agree on every product they purchase and on every order. The Terms and Conditions statement is required on every single product for the resellers.

We take this issue very seriously. If you have a suggestion to improve on this process, we are interested! Please send an email to HelpDesk@ecblend.com

New Study Finds that Vaping Does Not Expose Bystanders to Carbon Monoxide or Volatile Organic Compounds

A new study published online ahead of print in the journal *Nicotine and Tobacco Research* reports the results of an experiment in which vapor from electronic cigarettes was generated in an experimental chamber, either by a machine or by human users. The investigators measured the levels of nicotine, carbon monoxide, and 11 volatile organic compounds.

There were two major study findings:

1. The electronic cigarettes did not produce detectable levels of carbon monoxide or any of the 11 volatile organic compounds, which included benzene, toluene, chlorobenzene, ethylbenzene, xylene, styrene, naphthalene, 1,2-dichlorobenzene, 1,3-dichlorobenzene, and 1,4-dichlorobenzene.
2. The electronic cigarettes did produce nicotine, but the levels were 10 times lower than those from tobacco cigarettes.

The study summarizes the results as follows: "The study showed that e-cigarettes are a source of secondhand exposure to nicotine but not to combustion toxicants. The air concentrations of nicotine emitted by various brands of e-cigarettes ranged from 0.82 to 6.23 $\mu\text{g}/\text{m}^3$. The average concentration of nicotine resulting from smoking tobacco cigarettes was 10 times higher than from e-cigarettes (31.60 ± 6.91 vs. 3.32 ± 2.49 $\mu\text{g}/\text{m}^3$, respectively; $p = .0081$)."

The study concludes as follows: "Using an e-cigarette in indoor environments may involuntarily expose nonusers to nicotine but not to toxic tobacco-specific combustion products."

The Rest of the Story

Because only three brands of electronic cigarettes were tested, these results should be viewed as preliminary. Nevertheless, this study does add to the literature suggesting that electronic cigarettes do not emit toxic chemicals at levels that pose any substantial risk to bystanders. Further research is certainly warranted, but at the present time, any risk from secondhand vaping appears to be minimal.

Because nicotine is highly absorbed in the upper respiratory tract, it is as yet unclear whether vaping in public places produces significant exposure to nicotine among nonsmokers. Also, this study was conducted in an experimental chamber and it is not clear what real-life nicotine exposure would be in situations where vapers are using electronic cigarettes in a public place.

However, we do know that the nicotine exposure with passive

vaping is much lower than that associated with secondhand smoke (which is quite low to begin with). Since it appears that the nicotine exposure associated with passive vaping is about 10 times lower than that associated with passive smoking, we are probably talking about miniscule levels of nicotine exposure.

Moreover, there is now no question that electronic cigarettes are much safer than smoking and secondhand vaping is much safer than secondhand smoking.

In light of this study, it becomes unfathomable that researchers from NYU have declared that vaping is more hazardous than smoking. And it becomes just as unfathomable that a number of anti-smoking researchers and groups continue to claim that there is insufficient evidence to show that vaping is less hazardous than smoking.

This research confirms that the following groups, which claim that we don't have enough evidence to determine that vaping is safer than smoking, are making unfounded, inappropriate, and damaging arguments (click on links to view the claims being made by each group):

American Legacy Foundation

Food and Drug Administration

American Lung Association

Tobacco-Free Coalition of Hancock County

Tobacco-Free Coalition of Delaware County

Southern Nevada Health District

This research also demonstrates how irresponsible is the advice that the World Health Organization and Department of Health and Human Services are giving smokers (i.e., "do not quit using electronic cigarettes").

Posted by Michael Siegel at 9:04 AM 14 Comments 

 +1 Recommend this on Google

Pre-Clinical Study of Inhaled Propylene Glycol Found No Adverse Respiratory Effects

In 2007, researchers from Novartis Pharmaceuticals reported the results of a pre-clinical study designed to evaluate the safety of inhaled cyclosporine dissolved in propylene glycol by examining its acute effects in animals.

According to the study abstract: "The objective of these studies was to evaluate the potential toxicity of aerosolized cyclosporine formulated in propylene glycol when given by inhalation route to rats and dogs for 28 days. ... Endpoints used to evaluate potential toxicity of inhaled cyclosporine were clinical observations, body weight, food consumption, respiratory functions, toxicokinetics, and clinical/anatomic pathology. ... There was no unexpected systemic toxicity or clinically limiting local respiratory toxicity associated with inhalation exposure to cyclosporine inhalation solution at exposures up to 2.7 times the maximum human exposure in either rats or dogs. There were no respiratory or systemic effects of high doses of propylene glycol relative to air controls. These preclinical studies demonstrate the safety of aerosolized cyclosporine in propylene glycol and support its continued clinical investigation in patients undergoing allogeneic lung transplantation."

The Rest of the Story

This study provides pre-clinical evidence that the use of propylene glycol as an excipient for the delivery of drugs by inhalation appears to be acutely safe.

The study adds to existing evidence of the acute safety of inhaled propylene glycol. However, further study of the potential long-term effects of propylene glycol inhalation is necessary.

Nevertheless, these results help support the contention that the use of electronic cigarettes to quit smoking is a reasonable clinical approach to smoking cessation.

Industry Education

Occupation Professor

Introduction Dr. Siegel is a Professor in the Department of Community Health Sciences, Boston University School of Public Health. He has 25 years of experience in the field of tobacco control. He previously spent two years working at the Office on Smoking and Health at CDC, where he conducted research on secondhand smoke and cigarette advertising. He has published nearly 70 papers related to tobacco. He testified in the landmark Engle lawsuit against the tobacco companies, which resulted in an unprecedented \$145 billion verdict against the industry. He teaches social and behavioral sciences, mass communication and public health, and public health advocacy in the Masters of Public Health program.

The Rest of the Story: Tobacco News Analysis and Commentary

...Providing the whole story behind tobacco news.

Wednesday, December 18, 2013

Anti-Smoking Advocates are Scaring the Public About Nicotine Exposure Due to Passive Vaping, But Failing to Reveal that Exposure is Less than 0.08 Cigarette Equivalents

Several anti-smoking advocates are using the results of a new study which documented that vaping may produce low levels of nicotine in ambient air to argue that electronic cigarettes are a significant health hazard to bystanders.

On his tobacco blog, Stan Glantz writes that a new study "shows e-cig users exhale nicotine and fine particles into the air where bystanders are breathing." While acknowledging that this study found that nicotine levels from vaping were 10 times lower than nicotine levels from smoking, Glantz nevertheless concludes that: "e-cigarettes should not be allowed anywhere that cigarettes are not allowed."

Guided by alarmist claims like that above, a number of news articles warned that exposure to secondhand vapor is dangerous to health. For example, a *TIME* article warned that electronic cigarettes pose a "second-hand risk."

Elsewhere, researchers warned that nicotine exposure from passive vaping could damage the heart. According to this article, a Brown University researcher warned that: "long-term consumption of nicotine by e-cigarette smoking is likely to increase the risk of developing atherosclerosis by stimulating invasion of vascular smooth muscle cells." In other words, this researcher is claiming that passive vaping can lead to heart disease because of the exposure to nicotine.

The Rest of the Story

There is one thing that none of these anti-smoking researchers or advocates are telling the public. Exactly how much nicotine is a bystander exposed to, according to this research?

Well, the answer of course depends on the concentration of vapors in the establishment. But let's take an extreme example: a smoky

bar, filled with vapers, instead of smokers.

Assuming that the estimate from the study is correct, and that vaping produces 10 times lower the level of nicotine as smoking, then the estimate for the amount of nicotine inhaled by a bystander after 8 straight hours of exposure to a full room of vapers in a bar is which of the following? (In other words, how many cigarettes would a person have to smoke to get the same amount of nicotine as the bystander?)

- A. 80 cigarettes
- B. 8 cigarettes
- C. 0.8 cigarettes
- D. 0.08 cigarettes

The answer is ...

... D. 0.08 cigarettes

In order to inhale the equivalent amount of nicotine that would be inhaled by actively smoking one cigarette, a bystander would have to spend 12 days in a bar filled with e-cigarette vapor, at continuous exposure levels.

The reality is that right now, exposure to secondhand vaping is much lower than exposure to smoking in a smoky bar. A more realistic estimate is that a worker in a bar that allows vaping is exposed to at least 100 times lower exposure than with smoking (this assumes that the concentration of vapers in the bar is only one-tenth of that of smokers, averaged over the entire day).

Under these realistic conditions, even a full-time employee would be exposed to the equivalent amount of nicotine as actively smoking 0.008 cigarettes per day.

If that is the level of public health risk that warrants banning vaping in bars and restaurants, then there are a lot of other exposures that should be banned before touching vaping, based on these risk numbers.

To make it clear, I am not arguing that the door is shut and the case is over. Future research is still necessary to quantify the risks. I am simply pointing out that the actual evidence being used to support vaping bans - taken at face value - imply that advocates are alarming the public because bystanders may be exposed to about eight one-thousandths worth of the nicotine exposure in one cigarette if they spend a full day in a bar that allows vaping.

In my opinion, this makes a mockery of the scientific rigor of the movement and of the quality of evidence that we require before advocating for bans on personal behavior. Shouldn't we pride ourselves on a higher and more rigorous standard?

The Rest of the Story: Tobacco News Analysis and Commentary

...Providing the whole story behind tobacco news.

Thursday, January 30, 2014

New Study of Passive Vaping Shows No Evidence of a Significant Public Health Hazard

A new study published online ahead of print in the *International Journal of Hygiene and Environmental Health* is one of the first to examine levels of chemicals in the ambient air of a real-life setting in the presence of electronic cigarette use.

(See: Schober W, et al. Use of electronic cigarettes [e-cigarettes] impairs indoor air quality and increase FeNO levels of e-cigarette consumers. *International Journal of Hygiene and Environmental Health* 2013; doi: 10.1016/j.ijheh.2013.11.003.)

The study analyzed the levels of a large number of pollutants in the ambient air of a room in an office building during the presence of three smokers using electronic cigarettes. The room was moderately ventilated at 0.56 air changes per hour.

The most important results were as follows:

1. "Indoor concentrations of CO and CO₂ showed no difference between control and vaping periods."
2. "Formaldehyde, benzene and the pyrolysis products acrolein and acetone did not exceed background concentrations."
3. "With regard to the seven PAH classified as probable carcinogens by the IARC, the concentrations increased on average by 20% from 122.8 ng/m³ (control) to 147.3 ± 26.2 ng/m³."
4. "No significant increase was observed for the toxic and potentially carcinogenic elements cadmium, arsenic and thallium."
5. "The concentrations of elements and metals showed a 2.4-fold increase for aluminum." [However, there was no significant increase for any other metal, including copper, chromium,

nickel, lead, tin, vanadium, or zinc.]

The Rest of the Story

This study, although limited to only three brands of electronic cigarettes, provides reassuring evidence that there do not, at present, appear to be major concerns about substantial health hazards associated with secondhand exposure to electronic cigarettes.

Prior to this study, the most significant health concern regarding passive vaping was the possibility of exposure to carcinogenic and toxic aldehydes and pyrolysis products including formaldehyde, acrolein, and acetone. However, this study found no increase in concentrations of any of these pollutants under realistic (real-life) conditions.

Despite a small increase in polycyclic aromatic hydrocarbon concentrations, there were no significant increases for any of the known or probably carcinogenic compounds.

With the exception of aluminum, the concentrations of most metals were substantially lower during vaping than in the no vaping condition. Metals therefore do not appear to be a significant health issue at this point in time.

In summary, this study helps to alleviate concerns raised by prior research and does not raise any new concerns. While more research is clearly needed, especially because there are so many different brands of electronic cigarettes on the market, the current evidence does not point to any substantial health hazards associated with passive vaping.

In light of these findings, the best that the study authors could do to implicate electronic cigarettes as a human health hazard was to proclaim that "e-cigarettes are not emission-free." If that is the worst thing that these researchers can say, then it certainly doesn't appear to rise to the level of a known health hazard for which government intervention is necessary at this time.

There are clearly two ways to spin this study. One is to emphasize the study's reassuring findings that there were no substantial causes for serious concern. Another is to spin it as these authors did, stating their conclusion as follows:

"Analysis of indoor air quality during vaping sessions showed that e-cigarettes are not emission-free." This was the second time the authors used this phrasing to summarize their findings. Right now, that e-cigarettes are not emission free appears to be about the most alarming thing that can be said about them.