AEMSA **AMERICAN E-LIQUID** MANUFACTURING STANDARDS ASSOCIATION

Executive Summary:

- The Tobacco Control Act broadly defines a "tobacco product" to include substances that are derived from tobacco (e.g., nicotine). However, products that only contain such tobacco derived substances should not be regulated in the same manner as products that contain tobacco *per se* (e.g., cigarettes, smokeless tobacco and roll-your-own tobacco). Tobacco-containing products, especially those that are combusted (cigarettes), are the most harmful and dangerous products on the "continuum of risk" and should be treated as such. On the other hand, electronic cigarettes and the e-liquid that is used in them do not contain any tobacco and are demonstrably less harmful than tobacco-containing products. In terms of the "public health" (net population) consideration, there is significant evidence that demonstrates that these products (and especially the refillable e-cigarettes) are overwhelmingly used by adults who have transitioned away from smoking cigarettes to "vaping". There is little to no evidence that supports that these products are being used as a "gateway" to conventional, combustible cigarettes. Rather, they are being used as a "portal" away from smoking.

- The premarket authorization requirements set forth in Section 910 of the Tobacco Control Act should not apply to electronic cigarette and e-liquid products. Aside from "Big Tobacco" which has only recently entered this industry, most of the e-cigarette industry, especially within the refillable market, is made up of small businesses that will not be able to afford the costly premarket authorization requirements that currently apply to the regulated tobacco products. Any such premarket requirements will greatly impact thousands of small businesses and jobs across the country. Instead, the Deeming Regulation should focus on disclosure/notification requirements (*i.e.*, requiring e-cigarette companies disclose their ingredients, manufacturing process, vapor/aerosol chemistry to FDA), and establishing Good Manufacturing Practices.

- The original "Grandfather Date" of February 15, 2007 in the Tobacco Control Act should not apply to electronic cigarettes and other tobacco-derived products, as those products were not contemplated when Congress was drafting the legislation. Nowhere in the legislative history of the Tobacco Control Act was there any discussion or even mention of electronic cigarette products. That original Grandfather Date was chosen simply because that was the date the bill that eventually became the Tobacco Control Act was

first introduced in Congress. At that time, the U.S. electronic cigarette industry was nascent. Thus, only a few companies have access to potential "predicate" e-cigarette products that were being sold prior to February 15, 2007. Moreover, it would not make sense to apply the original Grandfather Date to such novel products that are only improving over time; the products on the market today are safer and cleaner compared to the rudimentary disposable models that may have been available on February 15, 2007.

All electronic cigarette and e-liquid products that are currently on the market should be allowed to remain on the market without obtaining FDA "premarket" approval. Part of OMB's mission is to ensure that economic impacts are assessed as part of regulatory decision-making process. Any requirement that would result in products being forced off the market would destroy the $2 billion e-cigarette industry, as well as the growing refillable market, which includes potentially thousands of small businesses and jobs across the country. The Deeming Regulation should allow for products already on the market to smoothly transition to fully regulated status, and create a reasonable premarket authorization process for new products that focuses on ingredient and manufacturing process disclosures to ensure purity and safety.

AEMSA welcomes opportunities to meet with Governmental agencies and legislators for the purposes of contributing to the formation and establishment of reasonable and realistic governmental regulation.

AEMSA advocates Reasonable, Realistic and Sustainable regulation for these products that promote Tobacco Harm Reduction.

AEMSA advocates electronic cigarette products for Adult use only and we support banning sales of these products to minors.

AEMSA is a Non-Profit Professional Trade Association
501(c)(6)

Website
http://www.aemsa.org/

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AEMSA Membership:

- General manufacturing (voting) members: 24
- Consumer Advocates (all volunteer): 4
- Subject Matter Experts (all highly credentialed): 3

Subject Matter Experts (SMEs):

- **Dr. Konstantinos Farsalinos** is a Cardiologist and Researcher at the Onassis Cardiac Surgery Center and at Medical Imaging Research Center in Leuven-Belgium. He has been dedicated to research on e-cigarettes since 2011.
- **Dr. Matthew Melvin** serves as the Group Leader of Enthalpy Analytical's Liquid Chromatography Laboratory. He has a Ph.D. in Organic Chemistry from Wake Forest University.
- **Dr. Kurt Kistler** is a Chemistry Instructor and Researcher at Penn State University. He has a Ph.D. in Physical Chemistry (Temple University) and an MS in organic chemistry (University of Illinois)

AEMSA and ENTHALPY ANALYTICAL working together:
http://www.enthalpy.com/index.html

"Enthalpy Analytical, Inc., a leader in the field of complex analytical measurement since 1993, is pleased announce they will be working with AEMSA to develop standard test methods and analytical criteria to help assure the ongoing quality and consistency of measurements made on their membership's e-liquid products. AEMSA's forward looking vision toward product stewardship and consumer safety are attitudes that align well with Enthalpy's corporate mission. We are looking forward to working closely with AEMSA." (Gene Gillman, Ph.D. – Enthalpy's Technical Director – 3/18/2013)

Enthalpy Analytical, Inc. Statement of Qualifications:
http://enthalpy.com/pdf/TSC-SOQ-2012.pdf

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Enthalpy Analytical, Inc. Accreditation: **http://enthalpy.com/pdf/A2LA-Scope-and-Certficate_3198-01_9-21-12.pdf**

Enthalpy is a member of CORESTA **www.coresta.org** - a nonprofit Association founded in 1956, "...purpose being to promote international cooperation in scientific research relative to tobacco" has 183 full members from 44 countries.

For 20 years, Enthalpy Analytical, Inc. has been professionally advancing the scientific evaluation, analysis, testing and techniques for tobacco, air quality and more. In recent years, Enthalpy became interested and involved in the analysis and evaluation of electronic cigarette related factors including nicotine delivery and liquid analysis.

AEMSA Standards: http://www.aemsa.org/standards/

All AEMSA Members agree to scheduled and unscheduled (unannounced) on-site inspections, maintaining evidentiary documentation, random product testing (including multi-level product testing and analysis), product traceability and more.

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Member Economic Impacts 2012 vs 2013:

AEMSA members were polled asking for voluntarily provided Economic Impacts in their operations for the years of 2012 and 2013 to demonstrate Growth. Twelve of the twenty-four Manufacturing Members (50% of total members) provided the following collective data:

	2012	2013
Gross Sales	$15,774,386	$56,323,300
Number of Employees	117	378
Number of Stores	12	35
Number of Labs	9	13
Number of Retail Customers	103,499	245,069
Number of Wholesale Customers	557	5455

All AEMSA Members range in size from 2 employees to over 115 employees. Total Member operations now exceed 30 labs.

The distribution of respondents is realistically representative for the range of membership businesses. The non-responding members are of comparable sizes, and employment, distribution. It is reasonable to estimate AEMSA Membership totals would yield numbers approximately doubling (or greater) those presented.

We believe the electronic cigarette refillable end of the industry may be substantially larger than any current estimation(s). Current estimates indicate 1,800 (possibly more) product specific vendors in the USA. While we estimate far fewer e-liquid manufacturers, most (if not all) 1,800+ product specific vendors sell refillable products. Some estimations indicate electronic cigarette products may outsell tobacco cigarette products within ten years (if not sooner).

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Mainstream Media – propaganda/rhetoric and dis/mis-information:

AEMSA finds the news/media and other commonly reported "information"/"data" on electronic cigarettes and/or refillable e-liquids predominantly unverified, unscientific, cherry-picked and/or represented in misleading and/or slanted directions.

"Little or no professional scientific/medical research":

- Well over 150 published and peer-reviewed studies
- http://www.aemsa.org/links/
- http://www.ecigarette-research.com/web/index.php
- Research consistently disproves common propaganda/rhetoric – products consistently proven to be less harmful than tobacco smoke by orders of magnitude.
- **Former Surgeon General, Dr. Richard Carmona**: http://www.businesswire.com/news/home/20130325005167/en/U.S.-Surgeon-General-Dr.-Richard-Carmona-Joins (Board of Directors of electronic cigarette manufacturer NJoy) - juxtaposes prevalent industry rhetoric
- **Former American Lung Association** CEO Chuck Connor becomes e-consultant http://www.usnews.com/news/articles/2013/09/27/american-lung-association-electronic-cigarettes-regulation - juxtaposes prevalent industry rhetoric.
- Electronic Cigarette e-liquids made to professional Standards (like AEMSA's) have not been found to have any identifiable carcinogens. Often referenced 2009 e-liquid analysis was not an American manufactured e-liquid and the industry has evolved and advanced exponentially since that 2009 product analysis.

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"Gateway to tobacco"

- We have seen no verifiable evidence of electronic cigarette use leading to tobacco use.
- Overwhelming evidence: Estimates indicate over 4 million electronic cigarette product consumers in the USA, possibly over 10 million product users globally – with unprecedented continuing growth.
- Product consumers are overwhelmingly representative of tobacco users switching to electronic cigarettes with the goal of complete tobacco replacement/cessation.

"Flavors Market to Youth"

- Fact: 99.99% of all Big Tobacco electronic cigarette products are made in only tobacco and menthol flavors
- Only Blu (Lorillard) sells flavors – requires $70 kit purchase (cost prohibitive to youth)
- Flavors are predominantly products of the refillable manufacturers like AEMSA members. These businesses are comparatively small Mom and Pop sized businesses lacking budgets to support national advertising.
- Liquor, coffee creamers, nicotine gums, and other adult products are sold and marketed in wide varieties of flavors – not accused of marketing to children. Adults like flavors.
- As consumers get away from combusting tobacco smoke, sense of taste and smell resumes quickly. Product sales trends indicate non-tobacco flavors far outsell tobacco flavors.
- Many/most consumers start with tobacco flavors seeking to replace the combustible flavors to which they are accustomed. Many/most switch to non-tobacco flavors.
- Most flavors are artificial flavoring (molecularly composed) – including most tobacco and menthol flavors -> no detectable distinction in risk between molecularly composed tobacco/menthol flavors vs. fruit/drink/etc. flavors. Certain specific flavoring ingredients demand further study

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Current evidence shows that adoption of e-cigarette use by non-smoking youngsters and adults is minimal. Therefore, any regulation to restrict flavors will cause harm to vapers while no public health benefit will be observed in any other group (including youngsters).

"Oral Ingestion" concerns:

- Liquids taste nothing like they smell, enjoyable flavor realizable only in the vapor. Liquids on tongue (even a single drop) taste HORRIBLE.
- Oral exposure to liquids highly likely to induce gag-reflex
- Oral ingestion will most likely induce vomiting (according to Dr. Farsalinos)

The referenced lethal dose of nicotine (60mg) has been recently challenged by Prof Mayer from university of Gratz who characterized such information as a myth coming from dubious experiments carried 150 years ago. He provided evidence that the lethal dose is between 500 and 1000mg, not taking into consideration that vomiting is the initial and immediate symptom from ingesting nicotine. AEMSA strongly supports proper labeling and child proof packages, and believes that the danger from handling e-liquids is not higher than many daily-used household products.

Other Considerations:

- On Thursday, December 19, 2013 – AEMSA will present in an FDA Listening Session for the third time this year. This presentation will provide to the FDA an AEMSA Sponsored medically conducted, monitored and analyzed Plasma Nicotine Absorption Levels (PNLs) Study. Independent Medical Researcher, and AEMSA SME, Dr. Konstantinos Farsalinos performed – and will personally present - this Study.
    - 420 blood samples were drawn from Study participants in a medical/clinical environment under strict, formal and documented Study protocols.
    - Results will document and provide the PNLs comparing

common cig-alike (cigarette look-a-like) products to more advanced/refillable products operating at a higher energy delivered level.
- Experienced electronic cigarette product user participants are compared to novice (tobacco cigarette consumers) participants for additional insight into PNLs comparisons, product substitution satisfaction, and product usage patterns.
- Professional statistical analysis will be applied to evaluate all results (including puff counts and durations obtainable on the advanced devices).
- Data from previously published studies delineating PNLs from combustible tobacco smoke will be presented for comparisons.

Dr. Farsalinos' Study will qualify to be published and peer-reviewed.

Mass produced "cig-alikes" (cigarette look-a-like products) are predominantly manufactured in China and imported. Certain cig-alike products (few and possibly only from one manufacturer) use e-liquids manufactured in the USA (subsequently shipped to China to become "prefilled" into the device cartridges). American made e-liquids, manufactured with verified good manufacturing practices (similar to AEMSA's) provide additional and easier monitoring and enforcement of all manufacturing controls (like ingredients quality controls, accuracy of content, manufacturing environments, child-proof and tamper evident packaging, evidentiary documentation, traceability and more).

Industry Questions/Issues Demanding Answers and/or awareness:
- Global Society has failed to effectively address/reduce the harms of tobacco use – can electronic cigarette technology change this?
- Tobacco Harm Reduction – don't we have a societal (domestic and/or global) responsibility to facilitate?

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- Replacing fiction with facts – electronic cigarettes myths/propaganda/rhetoric vs. factual reality.
- Published and Peer-Reviewed Medical and Scientific research negates unscientifically based rhetoric.
- Consumer driven industry's unprecedented growth, consumer driven innovations and Self Regulation – a new phenomenon – worthy of consideration in the regulatory process.
- Consumer volunteer implemented Self-Regulation - a first for any industry, especially one so closely related to the tobacco industry – another factor worthy of consideration in the regulatory process.
- Why are the American Cancer and Lung associations lobbying against THR/e-cigs AND/WHILE advocating against legislation banning sales to minors?
- Electronic cigarettes and their potential Economic Impacts including job creation, domestic manufacturing growth and exportation potential.
- THR alternatives, impacts on health care costs and/or health insurance premiums?
- All Public Health perspectives condemn tobacco use. Electronic cigarette products (especially refillable) offer the first consistently effective Harm Reducing alternative already being readily embraced by smokers (many now former smokers) – **why are regulatory processes looking to minimize/squelch the first ever proven effective approach to reducing combustible tobacco consumption and their related harms (first and second hand as well as those collaterally impacted like families and friends)?**
- While e-liquids are often made with liquid nicotine (extracted from tobacco), these liquids are also sold/purchased and consumed with zero nicotine content. Consumers who have successfully switched from tobacco, and subsequently reduced their nicotine consumption to

zero nicotine, could lose availability/accessibility – will these consumers be left with only available option to relapse back to deadly tobacco smoke to satisfy other Proven Habit/Behavioral factors of product use?

- **According to the Centers for Disease Control and Prevention (CDC): "Tobacco use is the single most preventable cause of disease, disability, and death in the United States." Why is our regulatory system not embracing, and seeking to maximize, the Harm Reductions benefits electronic cigarette products are offering?**

- **Some notable, credentialed and verifiable electronic cigarette research sources available:** Dr. Konstantinos Farsalinos, Dr. Michael Seigel, Dr. Riccardo Polosa, Dr. Joel Nitzkin, Dr. Brad Radu, Professor Etter, Dr. Chris Bullen, Dr. Murray Laugesen, Professor Igor Burstyn, ClearStream LIFE, ClearStream Air and many others.

AEMSA encourages and requests OMB/OIRA to delay the regulatory process to permit time for Industry and consumer feedback/input and to learn the Facts and Realities, bring more verifiable proven product information to regulators, allow Congress and/or Congressional Committees and/or Sub-Committees to effectively evaluate the TRUE Harm Reduction benefits and Economic Implications. The United States now has opportunities to lead the World in facilitating Real Tobacco Harm Reduction.

The AEMSA General Membership recently ratified a new agenda and budget for 2014. While work remains to verify the viability to accomplish all, the 2014 Agenda includes the following plans and intentions:

- Creation of a new 510(c)(3) entity to act as a unified funding vehicle to facilitate ongoing substantive Medical/Scientific Research on electronic cigarette products and potential health implications/impacts. Such could permit non-manufacturing

industry participants, and even consumers, to participate in AEMSA and Support the benefits of collective industry-wide Medical/Scientific Research funding.
- Flavoring initiative to begin more in-depth evaluation of any factors related to flavorings, flavoring ingredients, etc.
- Finalizing and posting revised 2014 version of the AEMSA Standards
- Creation of a dedicated division for establishing and maintaining Government relations, communications and facilitation(s).
- Continuing to grow the AEMSA membership:
    - AEMSA launched only a year ago with 8 manufacturing members, 12 short months later we have 24 manufacturing members. We anticipate continuing this growth rate and expanding the practice and implementation of verifiable and enforced good manufacturing practices through increased membership and participation.
    - Increasing Consumer participation in the organization as membership grows.
- More to be determined based on budget growth resulting from increased membership participation.

While nicotine, where included as an e-liquid ingredient, is currently derived from tobacco, there are other sources of nicotine (most commonly found in many night-shade plants). There also remain possibilities for advancements towards synthetic nicotine products which could potentially be substituted.

The electronic cigarette industry is a grass-roots industry. Big tobacco did not enter into the electronic cigarette industry until after realizing reductions to tobacco cigarette sales - directly resulting from increased electronic cigarette consumer substitutions. ALL electronic cigarette industry innovations are Consumer driven – including (but not limited to): new device safety features like over/under-charge protections, short

circuit protections, "smart" charging (cellphone technology), e-liquids quality/manufacturing controls thru verified application of good manufacturing practices (like AEMSA Standards), independent Medical/Scientific Research support and more.

*** Over-regulation of these products and industry will bring any and all product innovations, advancements and opportunities to further improve efficacy, further refining and improving Harm Reduction Benefits, and more all to a resounding and crashing halt. Additionally, over-regulation may well also put this electronic cigarette industry right back into the hands of Big Tobacco.*

There are those with conflicting agendas and many are disseminating misinformation, disinformation and/or intentionally grossly incomplete information. Most (if not all) of these propagations are unverified, non-science based, often untrue and are extremely misleading. Any regulators relying on such disseminations (and/or attempting regulation without actively evaluating verifiable studies) are doing themselves, their constituents and humanity overall an outrageous disservice. **Don't we owe it to our society, and all of humanity, to facilitate Tobacco Harm Reduction?**

Overregulation of Electronic Cigarettes can only guarantee tobacco HARM continues unabated.

AEMSA advocates electronic cigarettes and refillable e-liquid products for adult use only and supports banning sales to minors.

AEMSA advocates Reasonable, Realistic and Sustainable regulation that Promote Tobacco Harm Reduction.

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