Products and requests that the same be **done outside** the of the Act, as the Act does not provide the Agency to govern Vapor Products nor is helpful to attempt to use the very specific and rigid provisions of the Act which were narrowly tailored towards specific products and harms caused by smoking not vaping.

(5) FDA jurisdiction over e-cigarettes under the Tobacco Act framework vitiates Fairness Principles.

It is well settled that administrative law has adopted a balanced requirement of consistency dictating that, like circumstances should be treated alike (and, conversely, different circumstances should be treated differently) for regulatory purposes.[28] The Agency has incorporated this core principle into its regulatory policy with respect to other products. E-cigarettes are not analogous – in composition, consumer statistics, individual health risks, public health costs, or industry profile - to traditional cigarettes or cigars and, therefore, should not be regulated in the same manner.

Second, well-entrenched administrative law principles demand that the identifiable, quantifiable benefits of any Proposed Rule should outweigh (preferably, significantly outweigh) the identifiable, quantifiable costs or burdens of such regulation.[29] While an agency may exercise judgment without strictly relying upon quantifiable risks, especially where those risks have not been adequately studied, at a minimum, FDA must "offer a rational connection between the facts found and the choice made."[30] Here, as FDA directly acknowledges in its statement that "we do not currently have sufficient data about e-cigarettes and similar products to determine what effects they have on the public health,"[31] the cost-benefit calculation either cannot be adequately undertaken, or, based on current information discussed herein, overwhelmingly disfavors regulating e-cigarettes as "tobacco products."

In the Tobacco Act, Congress directed FDA in plain and unambiguous terms to undertake the enormously complex task of regulating tobacco products. FDA has made significant progress in doing so; coarsely distending that tailored authority to e-cigarettes would contradict Congress's language, intent, and entrenched fairness principles.

Craft does not oppose FDA authority to regulate e-cigarettes, e-liquid, accessories and components and parts, under future legislation rather, **Craft staunchly opposes FDA's authority to regulate the same under the Act**. Craft joins many others in the Vapor Products industry in advocating for Congress to

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[28] *See*, e.g., *Henry v. INS*, 74 F.3d 1, 6 (1st Cir. 1996) ("While a certain amount of asymmetry is lawful, an agency may not adopt significantly inconsistent policies").
[29] *See, e.g., Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).
[30] 947 F.2d at 1214, citing *Chemical Mfrs. Ass'n v. EPA*, 899 F.2d 344 (5th Cir. 1990).
[31] 79 Fed. Reg. at 23,144.

The Agency's attempt to use this Deeming Regulation to create jurisdiction where Congress did not authorize it should be rejected, either by FDA during its rulemaking process or by judicial challenge to the same. The Deeming Regulation's inadequate nexus between e-cigarettes and the clear statutory definition of tobacco products, would, again, fall particularly vulnerable to judicial review. Recent rulings have confirmed that courts "review questions of statutory construction de novo."[25] Importantly, a statute must be interpreted as a "symmetrical and coherent regulatory scheme, and fit, if possible, all parts into a harmonious whole."[26]

(4) The Deeming Regulations Requirement for Ingredient Listings is Inappropriate as Applied to E-cigs and E-liquids.

The Agency's Deeming Regulation would also improperly extend ingredient listing requirements set forth under §904(a) to newly deemed products, including e-cigs and possibly, e-liquids. While Craft is not opposed to ingredient listing requirements properly tailored to the Vapor Products industry, we firmly **oppose** the implementation of any requirements that mirror the unnecessarily rigorous and inflexible requirements imposed for cigarette ingredient listings. Specifically, the requirement under §904(c) that ingredient listing information be submitted whenever any additive, or the quantity of any additive, is changed is too rigid when applied to Vapor Products. Unlike cigarette manufacturing, the manufacturing of e-cigs and e-liquid is not yet a standardized or uniform process and the Act is not the proper vehicle to create such a framework for these products which are distinct and unique as compared to cigarettes. Section 904(a)(1) requires each cigarette manufacturer to submit a listing of all ingredients, including tobacco, substances, compounds and additives added by the manufacturer to the tobacco, paper, filter or other part of each tobacco product by brand and by quantity in each brand and sub-brand. Clearly, this in applicable to Vapor Products. Furthermore, in a November 2009 Guidance, FDA further clarified that the quantity of each ingredient "needs to be reported in consistent units across all products using an absolute measurement that is conserved during chemical reactions."[27]

While ingredient quantities and subsequent listing of cigarette products is standardized and
achievable in production, this requirement is far less feasible for Vapor Products at this time and is not applicable to these products, again, as the Act was never designed nor intended to govern Vapor Products. Therefore, Craft urges FDA to take this into account when developing ingredient listing requirements and guidance specific to Vapor

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[25] *King v. Burwell,* No. 14-1158 (decided July 22, 2014) (4th Cir.), citing *Orquera v. Ashcroft,* 357 F.3d 413, 418 (4th Cir. 2003).
[26] *Id.*
[27] Guidance for Industry, "Listing of Ingredients in Tobacco Products," (November 2009) *available at* http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM192053.pdf,
at 9.

e-cigarette liquid. The study concluded, "For all byproducts measured, electronic cigarettes produce very small exposures relative to tobacco cigarettes. The study indicates no apparent risk to human health from e-cigarette emissions based on the compounds analyzed."[21] Therefore, even the risks associated with secondhand smoke, not fully appreciated at the time of enactment but nonetheless an extension of Congress's intent to curb public health costs of combustible tobacco products, also do not and should not apply to e-cigarettes.

The Act clearly and unambiguously, narrowly targets one industry – the tobacco industry *not* the Vapor Products industry. This is made overtly clear, by once again, reviewing the Factual Findings in the Act. Specifically, Finding No. 29 states: "It is in the public interest for Congress to adopt legislation to address the public health crisis created by the actions of the tobacco industry."[22]

Therefore, the Agency should not be allowed to expand its "tobacco product" jurisdiction to include tobacco *alternatives*, without first satisfying the burden of proof to demonstrate that the Agency has a credible scientific basis for concluding that the health and safety risks of e-cigarettes are comparable to the well-known, highly specific and thoroughly documented health and safety risks of tobacco smoking clearly underlying the statute. Given the nascent status of the Vapor Industry and the Agency's failure to test these products in manner by which it could come to such a scientific conclusion, the Agency cannot, at this time, meet such a burden.[23] The Agency acknowledges that it cannot meet this burden by its own language in the Deeming Regulation which clearly states "we do not currently have sufficient data about e-cigarettes and similar products to determine what effect they have on the public health."[24] Absence of evidence on this critical point goes directly to the question of legislative intent behind Congress's grant of authority to FDA via the Act.

Congress gave FDA jurisdiction over "tobacco products" because of the well known, scientifically proven health risks and well studied, documented and determined public health costs of "tobacco products." Vapor Products are not "tobacco products" and were not a product category the drafters of the Act intended to regulate. Therefore, the Agency should not be allowed to regulate e-cigarettes, e-liquids or vapor accessories as "tobacco products" without first demonstrating that each specific type of Vapor Product has risks identical to the tobacco products set forth in the Act, which Congress clearly intended to regulate.

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[21] *Id.*

[22] Tobacco Act § 2 (Finding No. 29) (emphasis added).

[23] At the April 23, 2013 Food and Drug Law Institute Annual Conference, Grail Sipes, Counsel for FDA's CTP, indicated that there is a great deal we still do not know about e-cigarette use generally, not to mention all of the new product designs. In her words, "the Agency is in a place where a lot is not known about e-cigarettes and it is actively looking at research. However, there is not a solid body of evidence."

[24] 79 Fed. Reg. at 23,152.

"component" or vice versa. Our customers may purchase individual bottles of e-liquid, with or without nicotine but it is unclear as to whether our e-liquid is considered a component, an accessory or a tobacco product under the Deeming Regulation as the terms "component" and "accessory" are not defined. Without fail, zero-nicotine e-liquid or vaporizers that contain zero nicotine or nicotine not derived from tobacco cannot be deemed "tobacco products", "components" or an "accessory" in the context of the Act or the Deeming Regulation. Despite providing examples of components, parts, and accessories, the Deeming Regulation fails to provide any definition and states "FDA is not proposing definitions for components, parts, or accessories."[18] Due to the complex and technical nature of e-cigarettes (compared to the simplicity of already-regulated tobacco cigarettes), this lack of clarity is extremely confusing for e-cigarette companies. As discussed above, there are a variety of combinations in which e-cigarettes can be manufactured and bought, and without specific definitions it is difficult, if not impossible, to ensure compliance with any rule. While Craft firmly believes that FDA does not possess the authority to regulate e-cigarettes, if this Proposed Rule is finalized, it must develop exacting definitions specifically tailored to the e-cigarette industry to avoid rampant industry confusion.

(3) Vaping is Not Smoking and To Conflate the Two By Deeming Ecigs and E-liquids as "Tobacco Products" is Contrary to Public Policy

Recent studies firmly illustrate that there is no comparable risk between tobacco smoke and e-cigarette vapor when it comes to serious adverse health effects. A study by leading scientists at Drexel University in Philadelphia found that "In summary, analysis of the current state of knowledge about the chemistry of contaminants in liquids and aerosols associated with electronic cigarettes ***indicates that there is no evidence that vaping produces inhalable exposures to these contaminants at a level that would prompt measures to reduce exposure by the standards that are used to ensure safety of workplaces.*** Indeed, there is sufficient evidence to be reassured that there are no such risks from the broad range of the studied products, though the lack of quality control standards means that this cannot be assured for all products on the market. "[Emphasis Added][19].

This Drexel University study's results were echoed by another study, wherein researchers found that secondhand vapor from e-cigarettes poses no discernible risk to the public health. In October 2012, CHANGE, LLC at the Center for Air Resources Engineering and Science at Clarkson University in Potsdam, NY published an indoor air quality study.[20] The study compared harmful by-products commonly found in tobacco smoke versus the levels of those same compounds in several popular brands of vaporized

[18] 79 Fed. Reg. at 23,153.

[19] See, http://www.biomedcentral.com/1471-2458/14/18

[20] T.R. McAuley, P.K. Hopke, J. Zhao & S. Babaian, *Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality*, 24 INHAL TOXICOL. 850 (2012).

numerous reports about the growth of the zero nicotine products. Regardless, e-cigarettes containing nicotine synthesized in a lab or derived from alternative sources also would not be tobacco products, pursuant to the Act and FDA's interpretation of the same and therefore the Act would fail to even meet its own stated goal.

The Deeming Regulation plainly states, "FDA is not aware of any currently marketed tobacco product that does not contain nicotine," perhaps inadvertently signaling the loophole its Deeming Regulation creates for zero-nicotine products, a significant and growing segment of the market.[14] While the Deeming Regulation acknowledges that "the amount of nicotine in e-cigarettes varies among brands," it ignores that some e-cigarettes contain zero nicotine.[15] **Currently, nearly 30% of our e-liquid sales are attributed to zero-nicotine products, a percentage that continues to grow.** We believe the growth of the zero-nicotine products is related to the fact that many vapers have been using Vapor Products for some time, are now able to reduce their nicotine consumption as they switch to vapor over tobacco. The fact that some Vapor Products contain nicotine and that nicotine is sometimes, but not always, derived from tobacco is not sufficient as a matter of fact or law to bring e-cigs or e-liquid within the Act's definition of "tobacco products." Nicotine derived from tobacco is used to treat depression, Alzheimer's disease, and used in medicines as a tool to enhance cognitive abilities for those with cognitive deficits including memory loss and concentration issues. Deeming Vapor Products to be "tobacco products" simply because they contain nicotine (an alkaloid which commonly found in many plants in the Nightshade family, including potatoes, tomatoes and eggplant) which is derived from tobacco, is as inappropriate as deeming medicines used to treat Alzheimer's patients that contain the same nicotine as "tobacco products."

Additionally, the Deeming Regulation never defines what is an "electronic cigarette", "e-liquid" or "parts and components". Furthermore, the Deeming Regulation deems "parts and components," but not related accessories, "tobacco products." Components and parts are included as part of a finished tobacco product, or intended for consumer use in the consumption of a tobacco product.[16] The Deeming Regulation states that components and parts that would be covered include those items "sold separately or as part of kits sold or distributed for consumer use or further manufacturing or included as part of a finished tobacco product."[17] Here, FDA again defines terms inconsistent with e-cigarettes and their parts and components. More importantly, it is unclear as to what FDA is deeming a "component" or a "part". For example, it is unclear as to whether FDA is seeking to deem the vaporizer units themselves as a "tobacco product" and the e-liquid as a

[14] 79 Fed. Reg. at 23,194.
[15] *Id.* at 23,155.
[16] *Id.* at 23,153.
[17] *Id.* at 23,143.

accessory of a tobacco product." The Agency's Deeming Rule seeks to "deem products meeting the statutory definition of 'tobacco product,' except accessories of a proposed deemed tobacco product" to be subject to the Act.[11]

The Agency interprets the statutory definition of "tobacco products" to broadly cover a diverse range of currently marketed products such as "certain dissolvables, gels, hookah tobacco, electronic cigarettes, cigars, and pipe tobacco" as well as future products not currently marketed but oddly gives an exemption to "Premium Cigars" which are made of tobacco leaves, wrapped in tobacco leaves and light on fire and consumed via combustive activity.[12]

In the Deeming Regulation, the Agency states that "FDA envisions that there could be tobacco products developed in the future that provide nicotine delivery (e.g, via dermal or buccal absorption), similar to currently marketed medicinal nicotine products, but which are not marketed for therapeutic purposes. Such products would be 'tobacco products' and subject to FDA's chapter IX authorities should the deeming rule be finalized."[13] As such, FDA acknowledges certain jurisdictional limits emphasized by *Sottera* while ignoring the primary limit imposed by the statute - the definition of "tobacco product," i.e. "made or derived from tobacco."

Vapor Products such as e-cigs and e-liquids contain no tobacco; the only possible nexus that FDA could assert to deem e-cigarettes tobacco products, as defined, is that certain e-cigarettes contain varying levels of nicotine, and certain types of nicotine are derived from tobacco. However, many vapor products, including unfilled vaporizers hardware without e-liquid inside and e-liquids that have 0 mgs of nicotine, are far outside even this wrongfully asserted jurisdiction the Agency seeks to obtain.

The Deeming Regulations proposed definition of "tobacco product" to include e-cigarettes and possibly e-liquids would create an incongruous and inherent regulatory framework by wrongfully forcing some Vapor Products into the category of "tobacco product" while allowing others to exist outside the Act, which is where all Vapor Products should be. Contrary to assertions made by the Agency in the Deeming Regulations, zero-nicotine e-cigs and e-liquids are a very large and growing segment of the market and would not be subject to regulation. We find it disingenuous that the Agency claims to be unaware of this as we have attended educational seminars and conferences in the Vapor Industry which explicitly discuss the growth of the zero nicotine segment of the market and have seen Agency officials in attendance at many of these conferences. More importantly, there are

[11] 79 Fed. Reg. 23,142 (April 25, 2014) at 23,145.
[12] *Id.* at 23,143.
[13] *Id.*

however, is not the way the term smoke is commonly understood. Statutes and regulations should be construed under their "ordinary and plain meaning." [9]

Vapor, such as that which is emitted from an e-cig, containing traces of particulate matter, such as water evaporating from a tea kettle, is not ordinarily understood to be "smoke." Vapor products such as e-cigs do not function in manner akin to traditional cigarettes because they operate functions electrically rather than via combustion. Therefore, the vapor emitted by an e-cig would not fall within the definition of "smoke" or "smoking", nor would the use of the hardware used to vaporize an e-liquid and the e-liquid itself. Second, vaporizers such as e-cigs are battery powered and not "lighted" as that term is commonly understood. No flame is involved in its operation and therefore no smoke is produced. Accordingly, Vapor Products are do not fall within any reasonable definition or smoking or "tobacco product" as that term is defined by the Act and an attempt to broaden the limited authority Congress bestowed upon the Agency via the Act by applying a broad definition to these Vapor Products so that they would be deemed "tobacco products" is impermissible and contravenes public policy to the extent Vapor Products may be the most effective tool our society has in combating the scourge of disease and death caused by smoking and tobacco consumption.[10]

Vapor Products are largely reusable products that allow users to inhale vapor that contains nicotine and in many cases, vapor without nicotine, without exposure to or danger from fire, smoke, ash, or carbon monoxide or the thousands of chemical toxins and harmful and potential harmful constituents ("HPHCs") found in tobacco smoke.

As a result of these and other differences, there is no evidence of which we are aware (and certainly none which FDA has published) which would suggest that the risks and public health costs of e-cigarettes are in any way comparable to that of tobacco products, as defined in the Act based on the known costs of tobacco use. The same point applies to good manufacturing practices ("GMPs") and warning labels originating in the Act. The differences between e-cigarettes and tobacco cigarettes are so great that the GMP standards appropriate for one are plainly not appropriate for the other, providing further support that Congress acted only to regulate "tobacco products" as defined.

(2) Vapor Products Such as ECigs and E-Liquid Do Not Meet the Statutory Definition of "Tobacco Product" under the Act.

FDCA § 201 (rr) defines "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part or

[9] See, e.g., Winborne v. Va. Lottery, 278 Va. 142, 148, 677 S.E.2d 304, 306 (2009).
[10] See, http://nicotinepolicy.net/documents/letters/MargaretChan.pdf

products with tobacco products make such products part of the problem that Congress was trying to solve when it enacted the Act, when in fact, vapor products are one part of a possible solution to the harm caused by smoking.

Viewed under the lens of a public health perspective, provide adult smokers with an important alternative to harmful tobacco products including cigarettes. Mitch Zeller, Director for the Center for Tobacco Products has said, "If a current smoker, otherwise unable or unwilling to quit, completely substituted all of the combusting cigarettes that they smoked with an electronic cigarette, that person would probably be significantly reducing their risk."[6] Former US Surgeon General Richard Carmona has publically supported vaporizers as part of the solution to prevent death and disease caused by smoking as has Charles D. Connor, the former CEO and President of the American Lung Society has commented that statutes that treat vaping like smoking are "misguided" and "do a public health disservice, [by] discouraging smokers from switching to less-harmful electronic cigarettes that do not combust tobacco and therefore do not create second hand smoke."[7]

Vapor Products involve no burning or combustion ("smoking," as it stated in the language from the congressional findings) and are distinct from smoking. It is important that the Agency remember the vast differences in the chemical and physical properties between vapor and smoke, as well as the differences between Vapor Products and tobacco products and not stigmatize, improperly scare or cause confusion amongst consumers who are looking towards Vapor Products as an alternative to smoking and other forms of tobacco consumption. First, Vapor Products do not involve the "inhaling, or exhaling of smoke." Smoke is defined as "the gaseous products of burning carbonaceous materials made visible by the presence of small particles of carbon."[8] Furthermore to be sure, one definition of smoke is "fume or vapor often resulting from the action of heat on moisture." That,

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everyone with a physical impairment that precluded the performance of some isolated, unimportant, or particularly difficult manual task to qualify as disabled, the number of disabled Americans would surely have been much higher." Therefore, the Supreme Court held that the term "disabled" needed to be interpreted strictly to create a demanding standard for meeting the definition in order to give relevance to the specific legislative findings and purposes that motivate the ADA. Similarly, the term "tobacco product" should be interpreted strictly here and the Agency should not seek to circumvent the scope of authority that Congress has bestowed upon it with respect to the limited and narrow set of products that the Agency may regulate under the Act which do not include Vapor Products such as e-liquids, vaporizers and vapor accessories.

[6] *See,* http://thedianerehmshow.org/shows/2014-01-21/new-health-risks-cigarette-smoking/transcript

[7] *See,* http://www.foxandhoundsdaily.com/2014/02/e-cig-debate-guilt-association-2/

[8] MERRIAM-WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE UNABRIDGED 2152 (1993).

Regulate Vapor Products Under the Act Including E-cigs and E-liquids as They Are Not Tobacco Products.

A review of the Congressional factual findings supporting the Act clearly shows that Congress never intended to grant the Agency the authority to regulate these types of technology products pursuant to the Act. **The Act was specifically designed and created to address the serious adverse health effects of tobacco smoking**. This is most explicitly acknowledged in the factual findings which provide the predicate for the Act.[1] Specifically, Finding No. 13 states that tobacco use "causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking". Finding No. 14 indicates that a 50% reduction in youth smoking would "result in approximately $75,000,000,000 in savings attributable to reduced health care costs."[2] As we are sure you aware, agencies and courts generally defer to congressional legislative fact-finding[3] and of course we request that the Agency defer to the clear language of Finding No.'s 13 and 14. We note, Congress specifically cited in its findings of fact 400,000 annual deaths attributable to "tobacco use" as well as 8,600,000 chronic illnesses related to "smoking." Furthermore, Congress went on to specifically reference "smoking" in the context of potential cost savings associated with a 50% reduction in youth tobacco use, and at no point referenced or used the term "vaping". In fact, the distinctions between "vaping" and "smoking" are widely known as the two are in fact very different and should not be conflated or confused with one another.[4] Therefore, we caution that the Agency should not ascribe a broad meaning to the term "tobacco product" so as to improperly and impermissibly include products such as Vapor Products, which were not marketed during enactment, nor analyzed or studied in order to capture associated illnesses and public health costs in its findings of fact. Ascribing a broad meaning to the terms "tobacco product" and "smoking" would ignore Congress's clear and specific findings of fact motivating the Tobacco Act. [5] Furthermore, conflating vapor

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[1] *See* Tobacco Act § 2.

[2] *Id.*

[3] *See, e.g., Turner Broadcasting System, Inc. v. FCC (Turner II),* 520 U.S. 180, 199 (1997).

[4] *See, Opinion Letter of the Attorney General of the Commonwealth of Virginia* http://www.oag.state.va.us/Opinions%20and%20Legal%20Resources/Opinions/2010opns/10-029-Peace.pdf stating that "using an e-cigarette does not fall within the definition of "smoke" or "smoking" for purposes of § 15.2-2820 of the Code of Virginia.

[5] The Supreme Court of the United States of America, considered a similar issue regarding the term "disabled" in the landmark case, *Toyota Motor Mfg., Ky., Inc. v. Williams.* The Court in *Williams* interpreted Congress's definition of "disabled" strictly because Congress found that "some 43,000,000 Americans have one or more physical or mental disabilities." The Court, in rejecting arguments for a broader interpretation of the term "disabled"" reasoned that "if Congress intended

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Re: Docket No. FDA-2014-N-0189

Deeming Tobacco Products To Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

Dear Madam or Sir:

These comments are submitted on behalf of Craft Vapery, Inc. ("Craft"), a private company and market leader operating in the emerging vapor industry which distributes and sells both flavored, nicotine and non nicotine containing, liquid solutions for use with vapor products. Craft's liquid solutions for vapor products are commonly referred to as "e-liquid". Craft's e-liquid products are purchased by adult consumers both domestically and internationally and as such we are stakeholders who have carefully reviewed with great interest the proposed regulations to extend the Food and Drug Administration's ("FDA's" or the "Agency's") authority under the Family Smoking Prevention and Tobacco Control Act ("the Tobacco Act" or "the Act") to additional tobacco products ("Deeming Regulation") published as a Proposed Rule on April 24, 2014.

As a threshold matter, it is our position that (1) Vapor products including e-liquid are not "tobacco products" as that term "tobacco products" is defined by the Act nor should they be deemed "tobacco products" and; (2) Congress has never given the Agency the authority to regulate e-liquids, vaporizers- including electronic cigarettes ("e-cigs,") - and related accessories under the Act (collectively "Vapor Products"); (3) The Agency therefore has no legal authority to regulate Vapor Products, including e-liquid solutions that contain nicotine derived from tobacco, e-liquid solutions containing nicotine that is not derived from tobacco and e-liquid solutions that contain zero nicotine and (4) Vapor Products are more appropriately deemed technology products not, tobacco products. Vaporizers such as e-cigs are not made of tobacco and paper, but rather circuitry, wiring, micro processors, metal, and acrylics. They do not burn or combust tobacco, but rather heat e-liquid solutions to the point where they are vaporized. Similarly, e-liquids, even those that contain nicotine derived from tobacco, are not properly deemed "tobacco products" under the Act as is evident by a review of the Act and the factual findings supporting the Act and illuminating the intent of Congress in passing the Act.

(1) Congress Never Intended to Grant the Agency the Authority to Regulate Vapor Products and the Agency Does Not Have the Authority to

grant FDA appropriate and distinct authority to reasonably regulate e-cigarettes, which would be separately defined as the same would be more welcome, appropriate, proportional and beneficial to the commercial interests of the industry and the public's health.

a) If FDA proceeds to finalize the deeming rule to include e-cigarettes, it should do so using a new regulatory scheme.

Craft does not believe that the Tobacco Act gives FDA authority to regulate e-cigarettes, e-liquids, accessories, components or parts absent therapeutic claims. However, if FDA does proceed to finalize the proposed deeming rule to include Vapor Products, the rule will be subject to legal challenges in that regard and likely invalidated judicially. In the event FDA should nevertheless proceed to finalize the deeming regulation to include e-cigarettes, however, we believe the Agency should consider a new and different regulatory framework that acknowledges and accommodates the unique issues associated with e-cigarettes. Thus, without waiving its primary position that FDA has no authority over e-cigarettes, e-liquids or Vapor Products of any kind, Craft offers these comments regarding a potential modified framework for e-cigarettes.

Craft concurs with FDA regarding "distinctions in the hazards presented by various nicotine-delivery products."[32] Specifically, e-cigarettes "may be less hazardous than combustible products given the carcinogens in smoke and the dangers of secondhand smoke from combustible products."[33] Craft further concurs with FDA that e-cigarettes have potential to help smokers, particularly those who have limited success with currently approved cessation programs. Specifically, "emerging technologies such as the e-cigarette may have the potential to reduce the death and disease toll from overall tobacco product use depending on who uses the products and how they are used."[34]

Given the vast potential for harm reduction that e-cigarettes offer, it would be a serious mistake in public health policy to take any regulatory action that would have the effect of forcing these products off the market, such as subjecting them to requirements for substantial equivalence ("SE") or premarket tobacco product applications ("PMTA"). As acknowledged in the proposed rule, there are few if any "predicate" e-cigarettes upon which a substantial equivalence filing could be based.[35] If an eligible predicate could be found, it would likely be relatively primitive compared to modern e-cigarettes, and thus lacking certain important improvements, including those aimed at improving safety and consistency of

[32] 79 Fed. Reg. at 23,143.
[33] *Id.*
[34] *Id.* at 23,147.
[35] *Id.* at 23,176 ("FDA is not certain that manufacturers would in fact be able to use the SE pathway for many proposed deemed tobacco products because they may not be able to identify a viable predicate.")

delivery. In addition, if a predicate were found, it is likely that relatively few companies would have access to it, thus creating unfair competition.

Any regulations applied to e-cigarettes should be reasonably tailored to mitigate the economic impact on small and medium-sized businesses, such as ours, which comprise a majority of the nascent e-cigarette industry. FDA's initial Regulatory Flexibility Act analysis acknowledged that the rule would have a significant economic impact on a substantial number of small entities.[36] However, the Small Business Administration determined that the costs are likely understated and that the rule "may be disproportionately burdensome to small entities that do not have the legal resources of larger businesses."[37] If the Tobacco Act's "self-executing provisions" are applied to e-cigarettes, including pathways to market for new tobacco products, the economic impact will amount to making small and medium-sized companies like Craft obsolete, as we are simply unable to absorb the significant cost of such applications. We are well aware, as is the Agency, that the only companies that can reasonably afford a new product application are the pharmaceutical companies and the major tobacco companies who have been creating and adjusting internal Tobacco Act compliance programs since enactment. While compliance with the above provisions would be prohibitively expensive, these small and medium-sized businesses would also lack the ability to comply in the time frame provided and would therefore require an extension of the compliance period. As these businesses have no previous experience with FDA regulation, this extension would be needed to create compliance programs and to gather the required information. Therefore, if the Deeming Regulation became final, Craft supports a significant extension to the compliance period for small and medium-sized businesses. Craft recognizes the legal difficulties, as discussed in the proposed rule, of the notion of FDA "changing" the grandfather date by regulation. There are other ways, however, that FDA can act to eliminate, postpone, or soften the SE/PMTA requirements.

A. Investigational Use Exemption

FDA could use to tailor the regulation of e-cigarettes in accordance with their unique issues would be through the "investigational use" exemption:

> The Secretary may exempt tobacco products intended for investigational use from the provisions of this chapter under such conditions as the Secretary may by regulation prescribe.[38]

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[36] *Id.* at 23,195.

[37] *See* U.S. Small Business Administration, comments to Docket No. FDA-2014-N-0189 (Jun. 11, 2014), available at http://www.sba.gov/content/61114-deeming-tobacco-products-be-subject-federal-food-drug-and-cosmetic-act-amended-family-smoking-prevention-and-tobacco-contr.

[38] 21 U.S.C. § 387j(g).

Although not discussed in the proposed Deeming Regulation, this provision provides clear authority that could help solve many of the problems associated with the prospect of regulating e-cigarettes. Specifically, FDA could issue a regulation declaring all e-cigarettes to be "investigational use" tobacco products for an indefinite period of time so that the Agency and manufacturers may gather additional epidemiological and other health and safety data on e-cigarettes. Accordingly, FDA could at the same time exempt e-cigarettes from "new tobacco product" regulation, while imposing conditions that would prohibit adulterated or misbranded products and allow the Agency to gather information on the design, composition, and health and safety effects of e-cigarettes and to regulate their labeling and marketing. For example, FDA might consider imposing the following conditions (with appropriate compliance periods) for the investigational use exemption:

- Enforcement against products determined to be adulterated and misbranded, possibly including provision and enforcement of good manufacturing practices (GMP), if appropriately tailored to address manufacturing of e-cigarettes.
- Requiring vapor industry specific submission of ingredient listing and reporting of harmful and potentially harmful constituents.
- Requiring vapor industry specific registration and product listing for all e-cigarette products.
- Establishing 18 as the minimum age to purchase e-cigarettes.

FDA should wait until it gains further understanding of e-cigarettes and their potential for harm reduction, the Agency could consider implementation of a tobacco product standard for e-cigarettes in lieu of SE or PMTA. FDA could also issue guidance tailored to SE/PMTA submissions for e-cigarettes that outlines a streamlined approach consistent with the unique characteristics of e-cigs and Vapor Products.

(6) The Act Does Not Permit the Agency to Ban or Impose Restrictions on Flavored E-liquid.

As mentioned, Craft does not believe that the Agency has authority to regulate e-cigarettes or e-liquids under the Act and adopting the same arguments as stated above, Craft does not believe the Act allows the Agency to ban or place any restrictions on the use of flavored e-liquid. Craft agrees with the Agency that an e-cigarette is not a "cigarette," as defined in § 900(3) of the Act.[39] Therefore, as acknowledged in the proposed rule, the prohibition against flavors would not apply to e-cigarettes or e-liquid even if they were deemed to be tobacco products in a final

[39] *Id.* at 23,144.

rule. As a matter of law, therefore, FDA cannot, in the present rulemaking, take any action to prohibit, restrict, or limit the use of flavors in e-cigarettes or e-liquids as they are sold as stand alone products.

The Administrative Procedure Act (APA) requires that the Agency to provide adequate notice and justification for its proposed regulations.[40] Failure to do so requires the Agency to use a separate rulemaking to apply flavor bans to e-cigarettes. Justification for the inclusion of flavors into this Proposed Rule is lacking. The Proposed Rule simply states that some e-cigarettes are marketed with flavors which may be attractive to young people, and as such, FDA requests "comments, data, and research" to determine the Agency's role.[41] Further, FDA acknowledges that even if e-cigarettes were subject to this regulation, the existing statutory prohibition against characterizing flavors would not apply automatically to e-cigarettes.[42] As such, FDA requests data and information on this subject, as well.[43] This language is an acknowledgment FDA lacks information about flavoring in e-cigarettes and is merely a request for more information. In no way does this constitute a justification to include flavors in the Proposed or Final Rule.

Additionally adequate notice is also lacking As discussed previously, the Proposed Rule only requests information and fails to propose any sort of rule regarding flavorings. In fact, Mitch Zeller, Director of CTP, stated during an interview, "[i]n order to ban flavors in e-cigarettes that requires an entire separate rulemaking, which we can't do until we have regulatory authority over these products."[44] Nevertheless, because FDA has requested comments on establishing a standard for characterizing flavors for tobacco products other than cigarettes, Craft offers the brief comments below.

There is no credible evidence that flavors have negative effects on public health or are likely to initiate cigarette and/or dual use, including use by minors. Indeed, current research trends illustrate potential benefits of flavors. In a peer-reviewed and published article from December 2013, researchers found that most e-cigarette users switched between flavors on a daily basis or within the day, with former smokers switching more frequently.[45] According to survey respondents, variety in flavors is "very important" in reducing or quitting smoking.[46] The survey also found cigarette smokers typically began using tobacco flavored e-cigarettes, but as time

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[40] 5 U.S.C. § 553.
[41] 79 Fed. Reg. at 23,148.
[42] *Id.* at 23,147.
[43] *Id.*
[44] *Appeal growing among kids, FDA cracks down on 'wild west' of e-cigarettes*, PBS NEWS HOUR (April 24, 2014).
[45] Konstantinos Farsalinos, et al., *Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey*, INT'L J. ENVTL. RESEARCH & PUB. HEALTH 7272, 7275 (2013), *available at* http://www.mdpi.com/1660-4601/10/12/7272.
[46] *Id.* at 7276.

progressed these users switched to new non-tobacco flavors.[47] Finally, almost half of the respondents indicated that a reduction in available flavors would "increase craving[s] for tobacco cigarettes and would make reducing or completely substituting smoking less likely."[48] Another recent study determined that 65.5% of non-smoking vapers considered flavors other than tobacco important in helping them quit tobacco smoking.[49]

This research demonstrates flavors can play a crucial role in tobacco smoking cessation. Therefore, absent future development and sound confirmation of such evidence, CRAFT would oppose any FDA rulemaking intended to prohibit e-cigarette flavors. Many CRAFT members distinguish themselves from their competitors, including Big Tobacco, by creating unique e-liquid recipes incorporating flavors that appeal to their adult consumers. Craft only markets and sells our products, including those incorporating flavors, to adults and has invested great time and money to ensure that our products are not sold to minors whenever possible. Our products are intended for adult use only.

Conclusion

Craft does not believe FDA has authority to finalize the Proposed Rule as applied to Vapor Products including e-cigs, e-liquids or any Vapor Product. In the event FDA should nevertheless proceed to do so against the risk of judicial invalidation, Craft urges FDA to consider the issues and mitigating factors above.

If you have any questions, or care to discuss further, please contact me at Josh@CraftVapery.com.

Respectfully submitted,

CRAFT VAPERY, INC.

/s

Joshua Krane

President, Craft Vapery, Inc.

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[47] *Id.* at 7278.
[48] *Id.* at 7275-7276.
[49] *Big Suvery 2014 – Initial Findings Eliquid*, Vaping.com, http://vaping.com/data/big-survey-2014-initial-findings-eliquid (last visited July 31, 2014).

vapor delivery. In addition, if a predicate were found, it is likely that relatively few companies would have access to it, thus creating unfair competition.

Moreover, the Deeming Regulation deems "parts and components," but not related accessories, "tobacco products." Components and parts are included as part of a finished tobacco product, or intended for consumer use in the consumption of a tobacco product. 79 Fed. Reg. at 23,155.

The Deeming Regulation states that components and parts that would be covered include those items "sold separately or as part of kits sold or distributed for consumer use or further manufacturing or included as part of a finished tobacco product." Id.

By FDA's logic, the disposable containing nicotine eliquid is a tobacco product (presuming the nicotine was derived from tobacco), but the disposable containing zero-nicotine is not, even if they are manufactured by the same facility and contain the same ingredients, less nicotine. The individual zero-nicotine cartridges are not tobacco products, nor are the cases (as an "accessory"). Therefore, if FDA finalizes the Deeming Regulation as proposed, a single firm must comply with the "self-executing provisions in the Tobacco Control Act," for certain e-cigarettes but not for others. This presents a significant enforcement challenge for FDA and a regulatory minefield for the firm.

Craft does not, however, oppose FDA authority to regulate e-cigarettes under future legislation. In fact, prior to FDA's publication of the Deeming Regulation, CRAFT advocated that Congress grant FDA appropriate and distinct authority to reasonably regulate e-cigarettes, which would be separately defined. This remains CRAFT's position.

II. **Regulatory Impact Analysis (RIA)**

Pursuant to the Regulatory Flexibility Act, FDA must sufficiently analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA's comments state that it is FDA's position that the exemption pathway put into place by this rule provides an option that potentially reduces costs, and therefore the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities".
http://www.smallbusinessmajority.org/small-business-research/downloads/100912-micro-businessreport.
https://www.federalregister.gov/articles/2011/07/05/2011-16766/tobacco-products-exemptions-fromsubstantial-equivalence-requirements

This however is erroneous.

The Small Business Administration (SBA), in comments sent to the FDA, suggested that the Regulatory Flexibility Analysis performed by that agency lacked essential information required under the Regulatory Flexibility Act. Craft argues the same.

SBA's comments illustrated that the FDA failed to discuss the quantitative or qualitative costs of the proposed rule on many potentially affected small entities. FDA also did not

I. Congress Never Intended to Grant FDA Jurisdiction over Vapor Products and New Regulatory Authority Must and Should Be Established to Regulate Vapor Products

The Tobacco Act explicitly and narrowly targeted one industry – the tobacco industry: "It is in the public interest for Congress to adopt legislation to address the public health crisis created by the actions of the tobacco industry." See, Tobacco Act § 2 (Finding No. 29) (emphasis added). While Craft Vapery ("Craft") believes that regulations are needed which are specific to the vapor products category, Craft does not believe that The Tobacco Control Act is the appropriate vehicle for such regulations. It is undisputed that vapor products are compromised of different physical and chemical constituents then combustible tobacco products. Specific regulations, based on science and data which studies vapor products, which are distinct from tobacco products must serve as the predicate for any regulations and FDA has fallen woefully short in providing analysis which equates vapor products to the specific harms the Tobacco Control Act was intended to protect against.

Congress enacted the Tobacco Act to regulate tobacco and the smoking of tobacco because of the serious undisputed adverse health effects of tobacco smoking. Proof of this can be found throughout the Tobacco Act, starting explicitly in the factual findings which provide the predicate for the Act. *See* Tobacco Act § 2.

For example, Finding No. 13 states that "**tobacco use** causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to **smoking**" and Finding No. 14 indicates that a 50% reduction in **youth smoking** would "result in approximately $75,000,000,000 in savings attributable to reduced health care costs." See, Id.

FDA should and courts generally do defer to congressional fact-finding. *See, e.g., Turner Broadcasting System, Inc. v. FCC (Turner II),* 520 U.S. 180, 199 (1997). It is clear that the chemical and physical properties of vapor products such as e-liquid are vastly different than those of tobacco. Congress, could and should pass a "Vapor Control Act" as they are distinct from tobacco and need to be thought of, studied and regulated in a manner that is different from tobacco- because, they are in fact very different products then those that Congress intended to regulate via the Tobacco Control Act.

Given the potential for harm reduction that e-cigarettes may offer, it would be a serious mistake in public health policy and contrary to FDA's commitment to reduce tobacco harm, to take any regulatory action that would have the reverse effect. That is the consequence of subjecting these products to requirements for substantial equivalence ("SE") or premarket tobacco product applications ("PMTA") because these requirements, as written, will force e-cigarettes off the market. As acknowledged in the Proposed Rule, there are few if any "predicate" e-cigarettes upon which a substantial equivalence filing could be based. If an eligible predicate could be found, it would likely be relatively primitive compared to the sophisticated batteries, wiring, and airflow systems of modern e-cigarettes, and thus lack certain important improvements, including those aimed at improving safety and consistency of

VII. FDA Must Consider the Impact this Proposal Would Have on Small Entities, as Required by the Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA) requires agencies to examine the economic implications of a proposed rule for small entities.[5] Pursuant to the RFA, if a proposed rule would have a significant economic impact on a substantial number of small entities, agencies including FDA are required to conduct extensive research which analyzes regulatory options that would mitigate the detrimental economic effect any such burdensome rule would place on small business such as Craft. The Agency, impermissibly has never addressed any such an analysis in this docket.

CRAFT suggests the Agency to conduct a significant economic analysis of the proposals in this ANPRM as required by the RFA. This is necessary given the unnecessary and overwhelming economic burden Craft will suffer if forced to comply with this proposal. The FDA is required by the RFA to dedicate the resources necessary to understand the economic impact on small entities and as is clear, such an analysis has not yet been conducted. Historically, FDA has underestimated the negative impact of many of its proposed rules on small entities which has lead to concerns of the Small Business Administration's ("SBA") Office of Advocacy. Given that CRAFT's is a small entity, we request FDA conduct an accurate assessment of the economic impact this ANPRM proposal would have. We remain confident that the Agency can find regulatory options that would lessen the economic effect of the ANPRM on Craft as required by the RFA.

VIII. Conclusions

CRAFT with the caveats and for the reasons above, supports child-resistant packaging and common-sense product warnings related to e-liquids.

If you have any questions, or care to discuss further, please contact me at Josh@CraftVapery.com.

Respectfully submitted,

CRAFT VAPERY, INC.

/s

Joshua Krane

President, Craft Vapery, Inc.

[5] See, 5 U.S.C. §§ 601–612

mentioned above, statements which intentionally confuse e-liquid with a highly potent and poisonous form of "nicotine' aka "liquid nicotine", and similar statements which make unqualified claims that small amounts accidental exposure to e-liquid may cause death or serious harm. However, despite these objections, Craft believes that, in an abundance of caution, its best practice is to use safety caps on e-liquids which minimize accidental ingestion of e-liquid products.

Warnings such as "Contact Poison Control if Swallowed", or "Intended for Adult Use Only, Keep Out of Reach of Children", "Contains Ingredients Which May Cause Allergic Reaction", "Contains Nicotine" and "Consult Your Physician Before Use" are appropriate. Craft supports actions to the extent such warnings are applicable and beneficial in preventing accidental exposure to e-liquids. Warnings that exceed such statements are inappropriate are suggest harms which are not possible from accidental exposure must not be required. Craft requests that Vapor Products be treated, for the purpose of warning labels and statements, in a manner similar to other consumer products are not required to bear warnings about the toxicity of those specific products especially as such warnings would be untrue and misleading when applied to e-liquid.

C. Craft Supports S.142 Provided CPSC Promulgates Appropriate Regulations

For the reasons above, Craft supports enactment of the Child Nicotine Poison Prevention Act of 2015 (S. 142), which would require the Consumer Product Safety Commission ("CPSC") to promulgate regulations requiring child-resistant packaging for e-liquid. CPSC, with its long history of work on packaging issues of this kind, is the best agency to administer such regulations

Should FDA finalize regulations that would require child-resistant packaging for e-liquids, such regulations should make clear that an e-liquid manufacturer may rely on certification from its packaging supplier that proper testing has been conducted certifying that the required level of child resistance testing and packaging were provided by provided by the packaging supplier. Subsequently, after a package has satisfied the required testing requirements, each e-liquid manufacturer should not be required to test its products but rather should be allowed to rely upon the certifications of the providing bottler or packager. Craft objects to any testing methodology under CPSC protocol which requires the use of excessive large test groups of young children to the extent the same would be applied to the testing of e-liquid bottles. As the Agency is aware, use of such testing groups is time consuming, expensive, and unduly burdensome on small business entities like Craft.

specific potential and actual concerns surrounding Vapor Product. Craft supports regulation requiring child proof packaging.

A. CRAFT Has Already Adopted Standards Which Make This ANPRM Unnecessary.

Craft, in the absence of regulations, and like many other market leaders in the Vapor Products industry, spends significant resources to ensure our products contain appropriate warning labels and that our e-liquid is contained in child resistant packaging designed to avoid accidental exposure.

Given that Craft has already adopted child-resistant packaging and warning labels for its products such regulations are unnecessary and unduly burdensome. Many others in the vapor segment of the industry have voluntarily implemented child resistant packaging and warnings which have lead to a net positive effect resulting in a reduced number of exposure incidents in recent months. A review of the Comments of American Association of Poison Control Centers from this past summer indicates that rates of exposure dropped significantly from January 2015 through June 2015. [3] This drop off directly coincides with Craft's and the industry's increased efforts to adopt standards regarding child proof packaging and labeling.. The industry has demonstrated that voluntarily adoption of such practices by stakeholders is effective.[4] Therefore, is not necessary for the Agency to issue such regulations

Craft remains committed to sharing its best practices with the Agency and other companies to help ensure the industry safeguards consumer interests while providing adult smokers with a meaningful alternative to combustible cigarettes. Craft only sells its products to adults and believes Vapor Products should only be accessible to adults. As such, reasonable standards for e-liquid packaging should be consistent with current regulation of similar products not intended for ingestion and sold only to adults.

B. The Rate of Incidence of Accidental Exposure Are Miniscule As When Compared to Other Common Household Goods.

Craft believes that there are millions of American consumers using Vapor Products as of the date of this writing. E-liquid has become a common household good and yet that the incidence of accidental exposure to e-liquid is miniscule when analyzed in comparison to reports of accidental exposure of Americans to other common household goods. Craft strongly disagrees with false and misleading statements that have been made about the toxicity of e-liquid. This includes, as

[3] *See* Comments of American Association of Poison Control Centers at 1, July 17, 2015
[4] *See Id.*

questions, concerns and the penumbra of potential and actual benefits Vapor Products have to offer the public.

Such action is needed to properly inform the public, and help the Vapor Products segment of the market evolve by allowing for continual improvements in technology, innovation and accessibility to Vapor Products for adult consumers seeking an alternative to smoking.

V. Regulations Governing Packaging and Labeling of E-liquids Must Be Specifically Tailored to Address the Actual Risks Associated

To the extent FDA does not adopt the legal and policy arguments Craft has proffered in our opposition to the Agency's purported authority to regulate Vapor Products as suggested by the ANPRM and the Deeming Regulation, Craft repeats our previous comments on the Deeming Rule and cautions that any proposed rules must specifically consider the unique concerns, if any, posed by e-liquid and more broadly vapor products. FDA must simply apply regulations designed to curb the well known harms caused by cigarettes and other tobacco product to Vapor Products.

As such, in the event the Agency finalizes the Deeming Rule to include Vapor Products, it only should only do so by using a new regulatory framework. The current regulatory framework would unfairly burden Craft by requiring it to pay user fees, force Craft to comply with substantial equivalence requirements and make use of the pre-market approval pathways which were designed for tobacco products not Vapor Products. As the Agency knows, the rules governing these issues have been specifically promulgated to address the harms caused by smoking cigarettes and other tobacco products and were not designed to address Vapor Products which present different actual and potential harms and risk of harm.

VI. Craft Supports Specific, Narrowly Tailored, Distinct, Common Sense Warning Labels & Child-Resistant Packaging for E- Liquids

Craft encourages common-sense actions which are based on credible scientific evidence and specifically designed to curb any actual harm or threat of harm posed by accidental, exposure to e-liquids. Further, such regulations should be separate and distinct from those warnings which are required for tobacco products such as cigarettes. As stressed, e-liquid is not a tobacco product, and does not pose the same risk of harm as tobacco products. Regardless, Craft supports appropriate government action that requires purveyors of Vapor Products to inform consumers about any known actual or potential hazards. Additionally, Craft supports requirements that are specifically designed to prevent product misuse and abuse provided that such action is specifically tailored to address e-liquid and does not further conflate or confuse Vapor Products with dissimilar products. Craft supports the use of appropriate warning labels tailored to inform consumers about the

Continuing to call e-liquids "liquid nicotine" is scientifically inaccurate, knowingly deceptive and causes unwarranted and unsubstantiated public concern which unfairly stigmatizes Craft's products as liquid nicotine causing harm to Craft.

III. Craft Should Be Allowed to Share Emerging Scientific Data Which Suggests that Vapor Products Serve a Public Health Benefit

Craft does not make cessation or health claims regarding its Vapor Products. However, and without making cessation or health claims of any kind, Craft would be remiss if it did not alert the Agency to the many credible studies that have been produced which provide scientific evidence of the potential and actual benefits Vapor Products have with respect to cessation, individual health and public health. One recent study of particular importance regarding the product safety of Vapor Products as compared to cigarette use was cited and announced via Public Health England's (PHE) recent declaration labeling vaping as, an estimated, 95% safer than cigarette use.[2]

PHE's recent declaration is just one example which has been noted as credible evidence supporting the proposition that the harms posed by Vapor Products are vastly different than those posed by smoking tobacco products such as cigarettes.

It is of paramount importance that the Vapor Products industry be allowed to share information of this kind with the public without concern of being incorrectly categorized as a "drug" or a "device". Sharing such information with the public is not equivalent to making health or cessation claims. The ANPRM and the Deeming Rule as drafted are impermissibly and illegally burden the rights of Craft and others in the Vapor Products industry to exercise their First Amendment rights to free speech.

IV. The ANPRM Impermissibly Confuses Vapor Products with Tobacco Products

The ANPRM conflates and confuses Vapor Products with tobacco products and misleads the public into believing the two pose the same risk of harm and should therefore be regulated in exactly the same manner. The Agency has itself stated that it plans to analyze products according to a "continuum of risk" standard and recognizes that different products fall at different places on that continuum.

The Agency's inappropriate conflation of Vapor Products and tobacco products is harmful and misleading to the public at a crucial moment in time, when thoughtful, well researched and scientifically justifiable action is needed. FDA should seek to clarify the difference between Vapor Products and tobacco products so it properly begin to address

[2]See: http://www.ecig-westcoast.com/media/1000997/50606.pdf

[6] There is a growing body of credible, published research data supporting the very significant differences in the risks of tobacco smoking from any risks associated with Vaping Products;

[7] The ANPRM fails to recognize that vapor products are *not* "tobacco products" and, accordingly, should *not* be regulated as "tobacco products";

[8] The ANPRM would violate Craft's First Amendment rights as applying the modified risk tobacco product provisions of the Family Smoking Prevention and Tobacco Control Act to Vapor Products, would wrongfully prohibit Craft from truthfully informing our consumers that its Vapor Products contain no tobacco;

II. FDA Should Cease Improper Use of the term "Liquid Nicotine"

Craft objects to the Agency's improper use of the term "liquid nicotine" as it pertains to the ANPRM and by way of reference, to the Deeming Rule. It is a well known scientific fact, that nicotine is a liquid in its natural, unadulterated, physical and chemical state. To reference nicotine in its natural state as "liquid nicotine" is misleading as such nomenclature is usually applied to compounds which are *not* in their natural state. E-liquid, when measured at standard temperature and standard pressure is also a liquid compound but it is *not* simply nicotine. Referring to e-liquid as "liquid nicotine" is misleading, and confusing to the public and likely to cause unwarranted concern and unnecessary panic regarding Craft's e-liquid products thus harming Craft. Given that nicotine is a liquid in its natural state (unlike "liquid hydrogen" for example as hydrogen in its natural state is a gas) the Agency is knowingly using a nomenclature that is factually and scientifically incorrect and which causes harm to Craft by misleading the public into believing our products contain highly concentrated levels of pure nicotine levels when in fact our products do not.

To the contrary, Craft sells e-liquid which contain a highly diluted mixture of compounds that includes small, highly diluted amounts of nicotine in some, but not all products. Craft sells may e-liquids that contain zero milligrams of nicotine. Clearly, e-liquids which contain zero nicotine or highly diluted levels of nicotine is not the same as selling "nicotine" in the form or potency which is suggest but the term "liquid nicotine." FDA should not continue to label e-liquids "liquid nicotine", or mislead the public into thinking that e-liquid and liquid nicotine are equivalents. Similarly FDA should be sure to properly distinguish e-liquids from liquid nicotine and inform the public about the physical and chemical properties of each, as well as the differences between the two as they contain dissimilar properties and pose vastly different risks.

In response to this ANPRM, Craft incorporates by reference the objections we articulated in our August 8, 2014 comments the Deeming Rule[1].

I. FDA Lacks Authority to Regulate Vapor Products Including E-liquids Under the TCA

To be clear, it is Craft's position that the Agency may not legally and should not adopt the Deeming Rule or the ANPRM as applied to Vapor Products. Instead, the Agency must and should seek new and appropriately limited and specific authority from Congress to properly and effectively regulate Vapor Products separate and apart from tobacco products.

Central to Craft's objections to the Deeming Rule and equally applicable here with respect to the ANPRM are the facts that:

(1) Vapor products including e-liquid are not "tobacco products" as that term "tobacco products" is defined by the Act nor should they be deemed "tobacco products";

(2) Congress has never given the Agency the authority to regulate e-liquids, vaporizers- including electronic cigarettes ("e-cigs,") - and related accessories under the Act (collectively "Vapor Products");

(3) The Agency therefore has no legal authority to regulate Vapor Products, including e-liquid solutions that contain nicotine derived from tobacco, e-liquid solutions containing nicotine that is not derived from tobacco and e-liquid solutions that contain zero nicotine;

(4) Vapor Products are more appropriately deemed technology products not, tobacco products. Vaporizers such as e-cigs are not made of tobacco and paper, but rather circuitry, wiring, micro processors, metal, and acrylics. They do not burn or combust tobacco, but rather heat e-liquid solutions to the point where they are vaporized. Similarly, e-liquids, even those that contain nicotine derived from tobacco, are not properly deemed "tobacco products" under the Act as is evident by a review of the Act and the factual findings supporting the Act and illuminating the intent of Congress in passing the Act;

[5] Regulation of such products under the Act is unworkable, impractical, and unduly expensive;

[1] See ID No.FDA-2014-N-0189-8156, Docket No. FDA-2014-N-0189

CRAFT VAPERY.
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Via Electronic Submission

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

September 30, 2015

Re: Docket No. FDA-2014-N-0189

Deeming Tobacco Products To Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

Dear Madam or Sir:

The following comments are submitted on behalf of Craft Vapery, Inc. ("Craft"), a private company and market leader operating in the emerging vapor industry which distributes and sells both flavored, nicotine and non nicotine containing, liquid solutions for use with vapor products ("e-liquid") as well as various vaporizer systems which are used to vaporize e-liquid. Craft's e-liquid and vaporizer products are purchased by adult consumers both domestically and internationally. As such Craft are stakeholders who have carefully reviewed with great interest the Food and Drug Administration's ("FDA's" or "the Agency's") advance notice of proposed rulemaking ("ANPRM") related to nicotine exposure warnings and child-resistant packaging for "liquid nicotine", nicotine-containing e-liquid(s), and other tobacco products.

Craft appreciates and respects the Agency's thoughts and efforts with respect to this ANPRM. However, Craft's comments herein should in no way be construed as supportive of the Agency's currently-pending proposed rule ("the Deeming Rule") which seeks to extend FDA's authority under the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or "the Act") to vapor products including , but not limited to, the vaporizers and e-liquid which Craft currently sells.

Statement from specialists in nicotine science and public health policy

Dr Margaret Chan
Director General
World Health Organisation
Geneva

CC: FCTC Secretariat, Parties to the FCTC, WHO Regional Offices

26 May 2014

Dear Dr Chan

Reducing the toll of death and disease from tobacco – tobacco harm reduction and the Framework Convention on Tobacco Control (FCTC)

We are writing in advance of important negotiations on tobacco policy later in the year at the FCTC Sixth Conference of the Parties. The work of WHO and the FCTC remains vital in reducing the intolerable toll of cancer, cardiovascular disease and respiratory illnesses caused by tobacco use. As WHO has stated, up to one billion preventable tobacco-related premature deaths are possible in the 21st Century. Such a toll of death, disease and misery demands that we are relentless in our search for all possible practical, ethical and lawful ways to reduce this burden.

It is with concern therefore that a critical strategy appears to have been overlooked or even purposefully marginalised in preparations for FCTC COP-6. We refer to 'tobacco harm reduction' - the idea that the 1.3 billion people who currently smoke could do much less harm to their health if they consumed nicotine in low-risk, non-combustible form.

We have known for years that people 'smoke for the nicotine, but die from the smoke': the vast majority of the death and disease attributable to tobacco arises from inhalation of tar particles and toxic gases drawn into the lungs. There are now rapid developments in nicotine-based products that can effectively substitute for cigarettes but with very low risks. These include for example, e-cigarettes and other vapour products, low-nitrosamine smokeless tobacco such as snus, and other low-risk non-combustible nicotine or tobacco products that may become viable alternatives to smoking in the future. Taken together, these tobacco harm reduction products could play a significant role in meeting the 2025 UN non-communicable disease (NCD) objectives by driving down smoking prevalence and cigarette consumption. Indeed, it is hard to imagine major reductions in tobacco-related NCDs without the contribution of tobacco harm reduction. Even though most of us would prefer people to quit smoking and using nicotine altogether, experience suggests that many smokers cannot or choose not to give up nicotine and will continue to smoke if there is no safer alternative available that is acceptable to them.

We respectfully suggest that the following principles should underpin the public health approach to tobacco harm reduction, with global leadership from WHO:

1. *Tobacco harm reduction is part of the solution, not part of the problem.* It could make a significant contribution to reducing the global burden of non-communicable diseases caused by smoking, and do so much faster than conventional strategies. If regulators treat low-risk nicotine products as traditional tobacco products and seek to reduce their use without recognising their potential as low-risk alternatives to smoking, they are improperly defining them as part of the problem.

2. *Tobacco harm reduction policies should be evidence-based and proportionate to risk, and give due weight to the significant reductions in risk that are achieved when a smoker switches to a low risk nicotine product*. Regulation should be proportionate and balanced to exploit the considerable health opportunities, while managing residual risks. The architecture of the FCTC is not currently well suited to this purpose.

3. *On a precautionary basis, regulators should avoid support for measures that could have the perverse effect of prolonging cigarette consumption.* Policies that are excessively restrictive or burdensome on lower risk products can have the unintended consequence of protecting cigarettes from competition from less hazardous alternatives, and cause harm as a result. Every policy related to low risk, non-combustible nicotine products should be assessed for this risk.

4. *Targets and indicators for reduction of tobacco consumption should be aligned with the ultimate goal of reducing disease and premature death, not nicotine use* per se, *and therefore focus primarily on reducing smoking*. In designing targets for the non-communicable disease (NCD) framework or emerging Sustainable Development Goals it would be counterproductive and potentially harmful to include reduction of low-risk nicotine products, such as e-cigarettes, *within these targets*: instead these products should have an important role in *meeting the targets.*

5. *Tobacco harm reduction is strongly consistent with good public health policy and practice and it would be unethical and harmful to inhibit the option to switch to tobacco harm reduction products*. As the WHO's Ottawa Charter states: *"Health promotion is the process of enabling people to increase control over, and to improve, their health"*. Tobacco harm reduction allows people to control the risk associated with taking nicotine and to reduce it down to very low or negligible levels.

6. *It is counterproductive to ban the advertising of e-cigarettes and other low risk alternatives to smoking*. The case for banning tobacco advertising rests on the great harm that smoking causes, but no such argument applies to e-cigarettes, for example, which are far more likely to reduce harm by reducing smoking. Controls on advertising to non-smokers, and particularly to young people are certainly justified, but a total ban would have many negative effects, including protection of the cigarette market and implicit support for tobacco companies. It is possible to target advertising at existing smokers where the benefits are potentially huge and the risks minimal. It is inappropriate to apply Article 13 of the FCTC (Tobacco advertising, promotion and sponsorship) to these products.

7. *It is inappropriate to apply legislation designed to protect bystanders or workers from tobacco smoke to vapour products.* There is no evidence at present of material risk to health from vapour emitted from e-cigarettes. Decisions on whether it is permitted or banned in a particular space should rest with the owners or operators of public spaces, who can take a wide range of factors into account. Article 8 of the FCTC (Protection from exposure to tobacco smoke) should not be applied to these products at this time.
8. *The tax regime for nicotine products should reflect risk and be organised to create incentives for users to switch from smoking to low risk harm reduction products.* Excessive taxation of low risk products relative to combustible tobacco deters smokers from switching and will cause more smoking and harm than there otherwise would be.
9. *WHO and national governments should take a dispassionate view of scientific arguments, and not accept or promote flawed media or activist misinterpretations of data.* For example, much has been made of 'gateway effects', in which use of low-risk products would, it is claimed, lead to use of high-risk smoked products. We are unaware of any credible evidence that supports this conjecture. Indeed, similar arguments have been made about the use of smokeless tobacco in Scandinavia but the evidence is now clear that this product has made a significant contribution to reducing both smoking rates and tobacco-related disease, particularly among males.
10. *WHO and parties to the FCTC need credible objective scientific and policy assessments with an international perspective.* The WHO Study Group on Tobacco Product Regulation (TobReg) produced a series of high quality expert reports between 2005 and 2010. This committee should be constituted with world-class experts and tasked to provide further high-grade independent advice to the WHO and Parties on the issues raised above.

The potential for tobacco harm reduction products to reduce the burden of smoking related disease is very large, and these products could be among the most significant health innovations of the 21st Century – perhaps saving hundreds of millions of lives. The urge to control and suppress them as tobacco products should be resisted and instead regulation that is fit for purpose and designed to realise the potential should be championed by WHO. We are deeply concerned that the classification of these products as tobacco and their inclusion in the FCTC will do more harm than good, and obstruct efforts to meet the targets to reduce non-communicable disease we are all committed to. We hope that under your leadership, the WHO and FCTC will be in the vanguard of science-based, effective and ethical tobacco policy, embracing tobacco harm reduction.

We would be grateful for your considered reaction to these proposals, and we would like to request a meeting with you and relevant staff and a small delegation of signatories to this letter. This statement and any related information will be available on the Nicotine Science and Policy web site (http://nicotinepolicy.net) from 29 May 2014.

Yours sincerely,

Signatories this statement at 26 May 2014

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