UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

LEGATO VAPORS, LLC, JET SETTER JUICE LLC, ROCKY MOUNTAIN ECIGS LLC, AND DERB E CIGS INDIANA LLC Petitioners, v. DAVID COOK, DAVID COLEMAN, DALE GRUBB, AND MARJORIE MAGINN, IN THEIR OFFICIAL CAPACITIES FOR THE INDIANA ALCOHOL AND TOBACCO COMMISSION, MATT STRITTMATTER, IN HIS OFFICIAL CAPACITY AS THE SUPERINTENDENT OF THE INDIANA EXCISE POLICE, AND THE STATE OF INDIANA, Respondents, and RIGHT TO BE SMOKE-FREE COALITION, INC. Intervenor-Petitioners.	)	CASE NO. 1:15-CV-00761-SEB/TAB

PETITION FOR DECLARATORY
JUDGMENT AND INJUNCTIVE RELIEF

The Indiana General Assembly passed HEA 1432, as amended by SEA 463, to regulate the manufacture, distribution, and sale of e-liquids that are used in refillable electronic vapor ("e-vapor") devices (the acts are codified at IC 7.1-7 and are collectively referred to as the "statute"). Intervenor-Petitioner, the Right To Be Smoke-Free Coalition, Inc. ("Coalition"), a trade association of e-liquid manufacturers, distributors, and retailers who do business with Indiana entities and consumers, brings this challenge seeking to declare invalid and enjoin certain provisions of the statute because they violate the United States and Indiana Constitutions.

Preliminary Statement

1. The Indiana statute will drastically impact the e-liquid industry in Indiana. Since the statute became effective on July 1, 2015, e-vapor companies, including Coalition members, have been reviewing the statute and determining what steps will be necessary to comply with its provisions, which will include obtaining manufacturing permits, tobacco distributor licenses, and sales certificates before a statutory deadline of July 1, 2016. The Coalition members are fully committed to the safety of e-liquids, from manufacturing through distribution and sale, and would be able satisfy most of the statutory requirements aimed at ensuring that e-liquids sold to consumers in Indiana meet certain product and safety specifications (*e.g.*, selling e-liquid in containers with child-proof or tamper resistant packaging). The statute in several places, however, sets forth obligations that reach far beyond any reasonable level of regulatory oversight and imposes requirements that are unconstitutional in both their nature and scope.

2. Of particular concern are several provisions that, according to the statute, are intended to protect against the adulteration and contamination of e-liquids during the manufacturing process. These requirements apply not only to manufacturers located in Indiana, but also to any manufacturer operating *anywhere* in the United States. Moreover, retailers

selling e-liquid in Indiana will only be permitted to sell products that have been produced in compliance with these provisions. Specifically, the statute: (i) applies the Indiana commercial kitchen code to e-liquid production facilities; (ii) requires manufacturers to hire an independent security firm to install and operate a high level security system at each facility; and (iii) subjects manufacturers to extensive on-site audits and inspections. The statute also defines certain types of e-liquids to be a "tobacco product" and regulates distributors and retailers of such e-liquids under various parts of the state's general tobacco laws despite the fact that no e-liquids, in fact, contain tobacco. As shown in this Petition, each of these provisions is constitutionally infirm on one or more grounds.

3. Moreover, e-liquid manufacturers, distributors, and retailers have been forced to incur costs and expend resources as they make preparations to comply next year with the Indiana statute even though the U.S. Food and Drug Administration ("FDA") is expected to issue a comprehensive rule in 2016 that will regulate e-liquids and e-vapor devices and, specifically, will apply FDA regulations to these products that guard against adulteration and contamination. While the final rule will likely preempt much of Indiana's statute, the state chose not to defer to FDA and, instead, decided to subject the e-vapor industry to expensive and unattainable requirements that will eventually be rendered moot by federal action.

4. As a result, e-liquid manufacturers will have no choice but to abandon the Indiana market, distributors and retailers will no longer be able to sell those products, and Indiana consumers who use e-vapor devices will ultimately bear the burden of not having the selection or quality of e-liquid products that are available in other states. This is particularly disconcerting as many of these consumers have turned to e-vapor devices as a less risky alternative to traditional cigarettes and as a means to reduce or entirely eliminate cigarette smoking from their lives.

Parties

5. Intervenor-Petitioner Right To Be Smoke-Free Coalition, Inc. is a non-profit trade association incorporated under the laws of the District of Columbia. The Coalition's members consist of e-vapor companies that manufacture, distribute, and sell e-liquids, including doing business with Indiana entities and consumers. Specifically, the Coalition members operate manufacturing facilities outside of Indiana that produce e-liquids intended, in part, for distribution and sale in Indiana, or operate distributor/retail establishments that sell e-liquid into the state. Accordingly, the Coalition's members are subject to the challenged provisions set forth in the Indiana statute. The purpose of the Coalition is to advocate for reasonable and responsible laws and regulations for e-liquid and e-vapor products, and to promote the interests of the industry by engaging with governmental and other civic organizations.

6. Respondents David Cook and David Coleman are Chairman and Vice-Chairman, respectively, of the Indiana Alcohol and Tobacco Commission ("Commission"). Respondents Dale Grubb and Marjorie Maginn are Commissioners. Respondent Matt Strittmatter is the Superintendent of the Indiana Excise Police. Respondents are each being sued in their respective official capacities. They are charged under Indiana law with the implementation and enforcement of the challenged provisions in HEA 1432 and SEA 463.

7. Respondent State of Indiana is a body politic. The state, acting through its legislature, enacted HEA 1432 and SEA 463 as part of its governmental function authorized by applicable provisions of the Indiana Constitution and state statutes. The state is made a Respondent herein solely for the purpose of imposing an award of attorney's fees pursuant to 42 U.S.C. § 1988 in the event that Intervenor-Petitioner prevails in any aspect of its challenge to various portions of the statute.

8. The Respondents are acting, and have taken action, under color of state law with respect to the enactment, enforcement and/or supervision of the enforcement of the provisions of HEA 1432 and SEA 463 challenged herein by the Intervenor-Petitioner.

Jurisdiction and Venue

9. This suit alleges violations of the United States Constitution pursuant to 42 U.S.C. § 1983. This Court has federal question jurisdiction under 28 U.S.C. § 1331, and jurisdiction to address deprivations of constitutional rights under 28 U.S.C. § 1343.

10. This suit also alleges violations of the Indiana Constitution. This Court has diversity jurisdiction under 28 U.S.C. § 1332 and, in the alternative, supplemental jurisdiction under 28 U.S.C. § 1367, as the state claims arise out of the same case and controversy as those for which the Court has original jurisdiction.

11. This Court has jurisdiction to enter a declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, and provide further relief under 28 U.S.C. § 2202.

12. Venue is proper in this Court under 28 U.S.C. § 1391(b)(1)-(2), as all of the Respondents reside or exist within this judicial district, and a substantial part of the events giving rise to the claims asserted herein occurred in this judicial district.

Factual Background

Background

13. The e-vapor industry is relatively new to the marketplace, with e-vapor devices having only been commercially available in the United States for past five or six years. Since being introduced, however, their use has increased exponentially. Current estimates indicate that over 24 million people in the United States now use e-vaping devices (called “vaping”) and that this number is growing. One recent analysis by Wells Fargo estimated that annual e-vapor

market sales will reach $3.5 billion by the end of 2015. E-liquids and refillable e-vapor devices are expected to comprise at least $2.0 billion of those sales. There are hundreds, if not thousands, of e-liquid producers currently operating in the United States.

14. E-vapor devices are not traditional cigarettes, as they do not use tobacco and there is no combustion or smoke. Rather, the vapor produced by an e-vapor device is created when a battery activates a heating coil (called an atomizer) that vaporizes an e-liquid solution. Some e-vapor devices are designed to look like a traditional or "slim" cigarette – often called "cigalikes" – with a small, built-in cartridge containing pre-filled e-liquids. In industry parlance, these are referred to as "closed systems." Other devices differ in size and shape, being somewhat larger than cigalikes, and contain a refillable e-liquid tank. These are called "open systems" within the industry. Regardless, both types have the same purpose and functional utility – they allow the user to inhale the vaporized solution through a mouthpiece, with the aerosol providing a flavor and physical sensation similar to that of smoking a traditional cigarette.

15. E-liquids are manufactured using three or four primary ingredients – vegetable glycerin, propylene glycol, flavorings, and liquid nicotine. Nicotine is used in most, but not all, e-liquids. It is also important to note that HEA 1432 specifically approves of these ingredients for use in e-liquids (7.1-7-5-1). Further, these ingredients are used to manufacturer e-liquids for all types of devices. There is no material difference in composition between e-liquids used in pre-filled (or closed systems) and refillable devices (or open systems).

16. Recent scientific studies indicate that e-vapor devices and e-liquids do not pose the same health risks as traditional cigarettes and are substantially less harmful, in part due to the fact that e-liquids do not contain tobacco and do not result in combustion by-products, like particulate matter ("tar") and many other carcinogens and harmful substances. Moreover, as

demonstrated by the fast growing number of users, there is considerable evidence that many "vapers" have turned to e-vapor devices as a smoke-free alternative to reduce or quit smoking and to avoid the significant health hazards associated with traditional cigarettes.

FDA Regulation of E-Vapor Devices and E-Liquids

17. The FDA does not regulate e-vapor devices or e-liquids, but that is about to change. In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") (21 U.S.C. § 387-387u). This statute amended the Food, Drug and Cosmetic Act ("FDCA") to give FDA authority to regulate the manufacture, distribution, and marketing of "tobacco products." Unlike HEA 1432, which defines "tobacco product" as only those products that "contain tobacco" (7.1-6-1-3), the Tobacco Control Act reaches more broadly and also captures products "made or derived from tobacco" (21 U.S.C. § 321(rr)). As a result, the Tobacco Control Act covers products that use nicotine derived from tobacco leaf.

18. The Tobacco Control Act did not give FDA authority to immediately regulate all such products. Instead, the law only gave FDA the ability to regulate four specific types of tobacco products – cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco. These do not include e-vapor devices. However, at the same time, the statute also gave FDA authority to use its rulemaking procedures in the future to create a regulation that would "deem" other, currently unregulated tobacco products, as falling under the Tobacco Control Act.

19. On April 25, 2014, FDA issued a proposed "Deeming Regulation" that would impose extensive requirements on the manufacture, distribution, and marketing of various products, including e-vapor devices and e-liquids. *See* 79 Fed. Reg. 23,142. Specifically, if the Deeming Regulation is adopted as drafted, the newly covered tobacco products, including e-liquids that contain nicotine, would be subject to the same regulatory requirements as traditional

cigarettes – *i.e.*, a one-size-fits-all approach. This means that manufacturers of e-vapor devices and e-liquids will be required to, among other things, obtain pre-market authorization from FDA before selling their products and comply with a whole host of obligations, including labeling requirements, misbranding prohibitions, and reporting and recordkeeping provisions.

20. More relevant to this Petition, under the proposed rule, e-liquids would also become immediately subject to the Tobacco Control Act's provisions regarding adulteration and contamination (21 U.S.C. § 387b). Specifically, it would be unlawful for any e-liquid to be manufactured in "insanitary conditions" or contaminated with any "substance that may render the product injurious to health" – the very risks addressed by HEA 1432 and SEA 463. In the event of a violation, FDA would hold broad authority to bring a variety of administrative, civil, and criminal sanctions, including monetary damages and injunctions, against the offending e-liquid manufacturer (*see, e.g.*, 21 U.S.C. §§ 331, 332, 333; 21 C.F.R. §§ 17.1, 17.5-17.51). Moreover, FDA is directed to promulgate Good Manufacturing Practices ("GMPs") that would establish methods and controls for the manufacture of e-liquids (21 U.S.C. § 387f).

21. The Tobacco Control Act contains an express preemption clause that would preempt laws like Indiana's when the proposed Deeming Regulation is finalized. In particular, states are prohibited from establishing or continuing in effect any requirement that is different from, or in addition to, FDA standards governing, among other things, tobacco product standards, adulteration, or GMPs (21 U.S.C. § 387p). As a result, portions of HEA 1432 and SEA 463, including the commercial kitchen and security requirements as applied to e-liquids containing nicotine, would be preempted if the proposed Deeming Regulation is adopted as written. Given that most e-liquids contain nicotine, the scope of preemption would be broad. The Deeming Regulation is expected be issued as a final rule sometime in 2016.

The Indiana Statute - HEA 1432 and SEA 463

22. HEA 1432 (7.1-7), as amended by SEA 463, regulates the manufacturing (*e.g.*, mixing), bottling, selling, bartering, or importing of e-liquid in Indiana, as well as the sale, possession, and use of e-liquid products in Indiana. As articulated by the Indiana General Assembly, the stated purposes of the statute (7.1-7-1-2) are as follows:

a. ensuring the safety and security of e-liquid manufactured for sale in Indiana;

b. ensuring that e-liquid manufactured or sold in Indiana conforms to appropriate standards of identity, strength, quality, and purity; and

c. ensuring that e-liquid is not contaminated or adulterated by the inclusion of ingredients or other substances that might pose unreasonable threats to public health and safety.

23. Significantly, HEA 1432 regulates e-liquid manufacturing across the United States and is not limited to manufacturers located in Indiana. The statute defines "Manufacturer" to mean "any person or cooperative, located inside or outside Indiana, that is engaged in manufacturing e-liquid" (7.1-7-2-15). The term "Manufacturing" is defined, in turn, to mean "the process by which an e-liquid is mixed, bottled, packaged, and stored" (7.1-7-2-16).

24. HEA 1432, as amended by SEA 463, imposes an extensive and costly regulatory scheme on e-liquid manufacturers that covers much of the e-liquid supply chain and various aspects of the manufacturing process, with some of these provisions giving e-liquid companies no choice but to completely exit the Indiana market. These requirements include:

a. A manufacturer must obtain a permit from the Commission before mixing, bottling, packaging, or selling e-liquid to retailers or distributors in Indiana. The permit is valid for five years (7.1-7-4-1(a)).

b. A permit application must include plans for the construction and operation of the manufacturing facility that demonstrate that the facility design: (i) includes a clean room space for mixing, bottling, and packaging activities and (ii) is capable of meeting extensive security measures that can only be installed and operated by an independent security firm meeting specific qualifications (7.1-7-4-1(d)(1)).

c. The permit application must also include written consent from the manufacturer allowing the Commission to conduct "random" onsite facility audits, including of out-of-state plants, to carry-out physical inspections, sample e-liquid products, and review records (7.1-7-2-3, -4-1(d)(10), -6(b)(16)-(17)).

d. An e-liquid container must use a child-proof cap that has child-resistant effectiveness as required 16 C.F.R. § 1700.15(b)(1) and tamper evident packaging (7.1-7-4-6(b)(1)-(2)).

e. The e-liquid container's label must identify all active ingredients and include a separate designation if the e-liquid contains nicotine (7.1-7-4-6(b)(3)-(4)).

f. The label or container must include a batch number and means for the Commission to obtain the manufacturing date, as well as include a scannable code tied to the batch number (7.1-7-4-6(b)(5)-(6)).

g. The manufacturing facility must conduct all mixing and bottling activities in a clean room, and take all reasonable steps to ensure that an unauthorized ingredient is not included in any e-liquid produced for sale in Indiana (7.1-7-4-6(b)(8)-(9)).

h. The e-liquid can only be manufactured with, and comprised of, a few approved ingredients (*i.e.*, vegetable glycerin, propylene glycol, flavorings and nicotine) or any other ingredient approved by the Department or the FDA (7.1-7-5-1(a)).

i. The manufacturer must store and maintain production samples from each batch for not less than three years (7.1-7-4-6(b)(15)).

j. The manufacturer must consent to the Indiana state police department performing a national criminal history background check on any person listed on the application (7.1-7-4-1(d)(9)).

25. E-liquid retailers, whether located in Indiana or selling e-liquids over the internet, are also subject to regulation under the statute. Retailers cannot sell e-liquid in Indiana that was manufactured by an unpermitted manufacturer or was produced without compliance with the manufacturing protocols (7.1-7-6-2). Moreover, to the extent that a distributor or retailer sells an e-liquid that is also a "tobacco product," as that term is defined under Indiana law, they must obtain a tobacco distributor license or sales certificate (7.1-7-5-1(c)).

26. HEA 1432 provides for various penalties for manufacturers and retailers who violate the statute's provisions (7.1-7-6).

Open vs. Closed Systems

27. As noted above, there are generally two types of e-vaping systems currently on the market. Closed systems are typically manufactured to look like a traditional cigarette and are sold with a non-refillable sealed cartridge containing pre-filled e-liquid. Under HEA 1432, these are called "electronic cigarettes" (7.1-7-2-9).

28. Open systems, on the other hand, permit users to refill the cartridge with an e-liquid of their choice – *e.g.*, with a preferred flavor – that is purchased separately in a glass bottle or plastic container. Under HEA 1432, these are called "vapor pens" (7.1-7-2-23).

29. Inexplicably, HEA 1432 only regulates the manufacture of e-liquid that is used in open systems (*i.e.*, vapor pens). The statute exempts e-liquid that is manufactured for closed

systems (*i.e.*, electronic cigarettes) from regulation. Specifically, an "electronic cigarette" is defined as a "powered vaporizer that: (1) is the size and shape of a traditional cigarette; (2) uses a sealed non-refillable cartridge containing not more than four (4) milliliters of liquid; and (3) is intended to be vaporized and inhaled. The term does not include a vapor pen" (7.1-7-2-9). On the other hand, a "vapor pen" means "a powered vaporizer, other than an electronic cigarette, that converts e-liquid to a vapor intended for inhalation" (7.1-7-2-23).

30. HEA 1432's definition of "e-liquid" also embodies the distinction between e-liquid that is manufactured and sold for use in open versus closed systems. The statute defines "e-liquid" to mean a "substance that: (1) is intended to be vaporized and inhaled using a vapor pen; and (2) specifically excludes substances contained in non-refillable sealed cartridges of four (4) milliliters or less used in electronic cigarettes" (7.1-7-2-10).

31. HEA 1432, as amended by SEA 463, only regulates e-liquid that goes into open systems despite the fact that the ingredients and composition of e-liquid used in both open and closed devices is the same, and that there are companies who manufacture e-liquids for open systems that also sell the same e-liquids for closed devices. In short, there is no material difference between the e-liquids that are used in either system.

Clean Room Requirements and Commercial Kitchen Standards

32. To obtain a permit from the Commission, HEA 1432, as amended by SEA 463, requires that in-state or out-of-state e-liquid manufacturers must design and construct a "clean room" (7.1-7-4-1(d)). The term "clean room" is defined, in turn, to mean an "e-liquid manufacturing facility where: (1) the mixing and bottling activities are conducted in secure and sanitary conditions in a space that is kept in repair sufficient to prevent e-liquid from becoming contaminated; (2) equipment used in the manufacturing process is *easily cleanable*, as defined in

410 IAC 7-24-27(a), in such a way that it protects against contamination of e-liquid, e-liquid containers, or e-liquid packaging materials; and (3) the *cleaning and sanitizing* of equipment is consistent with the Indiana standards of public health and cleanliness that apply to *commercial kitchens* in the state" (7.1-7-2-4) (emphasis added).

33. To guard against potential adulteration or contamination, HEA 1432 does not set forth manufacturing standards that are designed to take into account the unique issues associated with the safe and proper mixing and bottling of e-liquids, or incorporate by reference industry standards or state of the art practices geared toward clean and sanitary manufacture of such products. Rather, the statute applies extensive regulations designed for an entirely separate and distinct industry – commercial kitchens (*e.g.*, restaurants) – that are aimed at preventing foodborne illnesses (*e.g.*, salmonella, listeria, and botulism) which are typically associated with meat, eggs, milk, fish, and other foods that can easily spoil (410 IAC 7-24). In fact, upon information and belief, it is unlikely that e-liquids can become contaminated with bacteria or microorganisms that could result in foodborne illness. E-liquids are not manufactured using food and, instead, contain ingredients that have antimicrobial properties which have been used in the past in hospitals and other settings requiring sterilization.

34. Indiana's commercial kitchen regulations define "easily cleanable" to be a "characteristic of a surface that: (1) allows effective removal of soil by normal cleaning methods; (2) is dependent on the material, design, construction, and installation of the surface; and (3) varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use" (410-IAC-7-24-27(a)). The regulations then set forth characteristics of food-contact surfaces that can be easily cleaned, such as: (1) they must be free of breaks, open seams, cracks,

or other imperfections; and (2) they can be cleaned without being disassembled, disassembled without tools, or disassembled using handheld tools (*e.g.*, screwdriver). The regulations also define the required characteristics of certain equipment, such as industrial washing machines that use detergents, water rinses, and sanitizing solutions to mechanically clean food contact surfaces (*e.g.*, a frozen dessert machine) (410 IAC 7-24-13, -229, -330).

35. Indiana's "cleaning and sanitizing" regulations also set forth detailed requirements for sanitizing food contact surfaces (*e.g.*, utensils) and equipment (*e.g.*, food mixers). These include, but are not limited to, the following (410 IAC 7-24-269 thru 304):

a. Use of, and specifications for, warewashing equipment, either manual (*e.g.*, high pressure sprayers or low-pressure detergent foamers) or mechanical (*e.g.*, enclosed washing machines).

b. Cleaning and sanitizing temperatures and exposure times, water pressures, types of detergents and cleaners, and chemical sanitizer pH and concentration levels.

c. Food contact surface cleaning frequency based on the type of food used, such as beef, fish, lamb, pork, or poultry.

Security Requirements

36. HEA 1432, as amended by SEA 463, requires e-liquid manufacturers to hire an independent security firm – *i.e.*, manufacturers are prohibited from installing and operating their own security equipment – to implement high level security measures at each production facility. Specifically, the security firm must have at least *one year* commercial experience in the following mandatory security features (7.1-7-4-1(d)) (emphasis added):

a. Video surveillance system design and installation with remote viewing capability from a secure facility.

b. Owning and operating a security monitoring station with ownership control and use of a redundant offsite backup security monitoring station.

c. Operating a facility that modifies commercial hollow metal doors, frames, and borrowed lights with authorization to apply the Underwriters Laboratories label.

37. The security firm also must have continuously employed someone for *not less than a year* who is certified by three organizations (7.1-7-2-14, -22, -4-1(d)) (emphasis added):

a. The International Door Association (IDA) – certified Rolling Steel Fire Door Technician. This certification is aimed at rolling steel fire door dealers, installers, and technicians. These types of doors protect property and minimize damage in case of accidental fires. To obtain a certificate, an individual must have two years of field experience with installing and servicing overhead rolling steel fire doors, complete a training course with an IDA-sanctioned trainer, obtain a minimum number of points on tests conducted in the field, and pass a comprehensive written examination administered by IDA.

b. The Door and Hardware Institute – Architectural Hardware Consultant (AHCs). AHCs provide specification advice to architects, contractors, and building owners regarding proper hardware items to comply with fire, safety, accessibility, and building code requirements. Certification requires that an individual complete 13 courses and pass a two-day examination.

c. Associated Locksmiths of America – certified professional locksmith (CPL). To become a CPL, an individual must pass an examination on ten mandatory categories and an additional twelve elective categories.

38. Additional mandatory security features under HEA 1432 and SEA 463 include (7.1-7-4-6(10)-(15)):

a. E-liquid must be stored in a secure area accessible only by authorized personnel.

b. All areas where e-liquid is mixed, bottled, packaged, and stored must be remotely monitored by a security system at the facility.

c. The manufacturer must have an exclusive high security key system that limits access to areas where e-liquid is mixed, bottled, packaged, or stored.

d. The manufacturing facility must be subject to twenty-four hour video recording where e-liquid is mixed, bottled, packaged, and stored. Video recordings must be retained at least for thirty days.

39. Upon information and belief, there are no independent security firms that have continuously satisfied all of these requirements anywhere in the United States since before July 2015, or that provide geographical coverage sufficient to maintain and repair security equipment in each locality where an out-of-state facility is located.

Facility Audits

40. Under HEA 1432, as amended by SEA 463, the Commission is authorized to conduct "random audits" of each manufacturer's facilities (7.1-7-4-6(b)(16)-(17)). The term "audit" means "a procedure performed by the commission, including inspection of manufacturing facilities and preparation areas, review of required records, compliance checks, and auditing of samples of e-liquid" (7.1-7-2-3).

41. The statute empowers the Commission, therefore, to "enter . . . the premises" and conduct a "physical inspection" of out-of-state e-liquid manufacturers (*e.g.*, an Indiana inspector traveling to and auditing a California facility) (7.1-7-4-1(b)).

Classification of E-Liquid as a "Tobacco Product"

42. HEA 1432 defines "tobacco product" to include "e-liquid that contains tobacco" and is "intended for human consumption" (7.1-1-3-47.5). *See also* 7.1-6-1-3 (defining "tobacco product" as a "product that contains tobacco and is intended for human consumption").

43. Because e-liquid is considered to be a tobacco product (without any regard for whether the liquid actually contains tobacco), distributors and retailers in Indiana must obtain a valid tobacco distributor license or sales certificate under the state's general tobacco regulations (7.1-7-5-1(c)). Distributor licenses are issued by the Department of Revenue (6-7-2-8) and the sales certificates are granted by the Commission (7.1-3-18.5-1).

44. E-liquids intended for use in both open and closed systems, however, do not contain tobacco. Nicotine is a naturally-occurring chemical that exists separate and apart from the tobacco plant. Nicotine can be derived from materials other than tobacco, such as tomatoes, eggplants, and potatoes. In fact, nicotine can be synthesized in a laboratory. Moreover, unlike tobacco, nicotine is not an organic substance, nor is it an agricultural product. Rather, it is substance that, after being extracted from the tobacco plant or other source, goes through a complex purification process. At that point, even if the nicotine was derived from tobacco, it is chemically and materially distinct from its source. Indeed, FDA does not consider smoking cessation products that contain nicotine, like patches and gum, to be tobacco products.

COUNT ONE

Violation of Commerce Clause (Extraterritoriality)
Commercial Kitchen, Security, and Audit Requirements

45. Petitioner reasserts and incorporates by reference each of the above paragraphs.

46. Article I, Section 8 of the United States Constitution grants to Congress the exclusive authority to regulate interstate commerce. Under the Dormant Commerce Clause,

states are precluded from applying a state statute to commerce that takes place wholly outside of the state or otherwise controls conduct beyond the boundaries of the state. A state statute that results in extraterritorial regulation is *per se* unconstitutional.

47. HEA 1432 regulates e-liquid manufacturers both in Indiana and across the United States. The statute explicitly defines "Manufacturer" to mean "any person or cooperative, located inside or *outside* Indiana, that is engaged in manufacturing e-liquid" (7.1-7-2-15) (emphasis added).

48. As part of the permitting process, HEA 1432, as amended by SEA 463, requires manufacturers to submit "[p]lans for the construction and operation of a facility" that meets various requirements (7.1-7-4-1(d)(1)). Manufacturers must not only build a "clean room" that complies with Indiana's commercial kitchen specifications (7.1-7-2-4), but also hire an independent security firm with the proper certifications to install and operate a high level security system at the production facility (7.1-7-4-1(d)).

49. The vast majority of the e-liquid manufacturers in the United States, including members of the Coalition, are located outside Indiana. To comply with the statute, these manufacturers will either have to retrofit their facilities to comply with the commercial kitchen code and the independent security firm/high level security requirements, or build an entirely new production facility to Indiana's specifications. Under either scenario, however, Indiana seeks to directly regulate manufacturing activities taking place wholly outside the state.

50. Out-of-state manufacturers selling into Indiana will have no choice but to apply these standards to their entire production facility, which will necessarily cover products that are produced for sale in other states. In other words, no manufacturer will build and operate two separate facilities – one dedicated to Indiana e-liquids and one committed to products sold in any

of the other forty-nine states – with only an Indiana-related facility complying with the commercial kitchen and independent security firm/high level security requirements. As a practical matter, products bound for other states will have to be produced under the same commercial kitchen and security regime as e-liquids heading for sale in Indiana.

51. HEA 1432 and SEA 463 also result in extraterritorial regulation with regard to the on-site audits. The statute allows the Commission to conduct "random" on-site inspections of out-of-state manufacturers, including mixing and bottling areas and security systems. This means that Commission inspectors will necessarily be auditing manufacturing facilities and processes that are used to produce e-liquids for sale wholly outside Indiana.

52. Indiana's statute also sets the *de facto* standard for e-liquid manufacturing and security across the country even if other states have made policy choices not to impose such burdens on the e-liquid industry. Indeed, many states already regulate e-vapor devices and e-liquids, with most focusing on age and sales location restrictions (*e.g.*, no sales to minors or prohibiting vaping in public places like restaurants, offices, etc.) and requiring child-resistant packaging. At least one state also requires e-liquid manufacturers to obtain a license to sell such products. However, no state statute or regulation governs any aspect of the production or manufacturing process, let alone imposes commercial kitchen, independent security firm, or audit provisions like those found in the Indiana statute. And there are many reasons that other states might decide not to impose such requirements – *e.g.*, they might conclude that the risk of contamination is low, that any such risks are outweighed by the impact of driving e-liquid manufacturers out of their respective markets, or that there is a potential public health benefit in that e-vapor products may provide an alternative for cigarette smokers. Regardless, Indiana's

law effectively trumps less intrusive state regulatory schemes, thereby projecting Indiana's policy choices on to all other states.

53. If other states decide to regulate manufacturing and security aspects of e-liquid production, there is also the potential for conflict between those laws and Indiana's statute. Even a cursory review of Indiana's commercial kitchen standards and the security requirements reveal extremely detailed provisions. Unless other states adopt Indiana's statute verbatim, e-liquid manufacturers would likely be subject to inconsistent regulatory obligations.

54. Finally, out-of-state retailers – for example, retailers selling e-liquids over the internet to Indiana residents – will be unable to sell e-liquids that are produced by manufacturers who fail to comply with these requirements. From that perspective, their businesses and sales activities are also being directly regulated by the Indiana statute.

55. The commercial kitchen, security, and audit requirements imposed by HEA 1432 and SEA 463 violate the Commerce Clause and the prohibition on extraterritorial regulation. Thus, those provisions should be declared unconstitutional and enjoined in their entirety to the extent that they apply to e-liquid manufacturers and retailers outside of Indiana.

COUNT TWO

Violation of Due Process Clause
Independent Security Firm Requirements

56. Petitioner reasserts and incorporates by reference each of the above paragraphs.

57. The Due Process Clause of the Fifth Amendment of the United States Constitution, as incorporated by the Fourteenth Amendment, requires that state laws must have a rational relationship to a legitimate state interest. A state law whose chosen means do not bear a rational relationship to the asserted state interest is arbitrary and thus unconstitutional.

58. There are hundreds, if not thousands, of e-liquid manufacturers across the country, and for any of these companies who wish to do business in Indiana, including Coalition members, they will be required to hire an independent security firm meeting the burdensome certification and high level security requirements set forth in HEA 1432 and SEA 463. These manufacturers are not permitted to install and/or operate their own security systems.

59. Upon information and belief, there are no independent security firms in the United States who have met all of the certification provisions and other requirements laid out in the Indiana statute over the past year. Further, to provide e-liquid manufacturers with adequate security services, there will need to be qualifying firms in each locality where a manufacturer has a production facility so that the security firm may quickly and efficiently operate, maintain, and repair security equipment (*e.g.*, doors, locks, video cameras). Because these types of firms and/or geographical coverage do not exist in the United States, it will be impossible for manufacturers to comply with the statute's security requirements.

60. There is also no indication that an independent security firm with the requisite certifications and qualifications is needed to protect against any intentional tampering or sabotage – the only risks that the security requirements appear to address – that would result in an adulterated or contaminated e-liquid, or that manufacturers could not install and operate adequate security systems themselves. Indeed, at least one certification – requiring a certified Rolling Steel Fire Door Technician – serves no purpose in protecting against adulteration and contamination. Imposing costly, if not unattainable, security requirements while depriving manufacturers of their right to install or manage their own security systems is completely arbitrary and lacks a foundation for the proposition that an independent security consultant delivers more efficacious security than a manufacturer who manages its own system.

61. Finally, retailers in Indiana or those marketing e-liquids over the internet will not be able to sell e-liquids that are not produced in compliance with the security provisions. Accordingly, such retailers also suffer a constitutional injury where e-liquid manufacturers cannot comply with the security obligations.

62. The independent security firm requirements violate the Due Process Clause. Accordingly, those provisions should be declared void and unconstitutional.

COUNT THREE

Violation of Commerce Clause (*Pike* Balancing)
Commercial Kitchen and Security Requirements

63. Petitioner reasserts and incorporates by reference each of the above paragraphs.

64. Article I, Section 8 of the United States Constitution grants to Congress the exclusive authority to regulate interstate commerce. Under the Dormant Commerce Clause, a state statute is prohibited from imposing burdens on interstate commerce that are clearly excessive to the putative local benefits sought under the statute.

65. Even if HEA 1432, as amended by SEA 463, is not deemed as directly regulating out-of-state manufacturing activities, the statute will still significantly burden interstate commerce. As noted above, out-of-state manufacturers will not be able to comply with the independent security firm/high level security requirements as there are no known security firms that qualify under the statute. Further, even if there are a few such firms around the country, they would not provide a sufficient geographical footprint to adequately service the majority of e-liquid manufacturers. Under these circumstances, out-of-state manufacturers will not be able to comply with the statute and will, therefore, be forced to pull out of the Indiana market. This will then, in turn, adversely impact businesses distributing and selling e-liquids into the state.

66. Moreover, even if compliance with the security requirements is possible, manufacturers outside of Indiana will still need to either retrofit their facilities or build entirely new production plants to meet the commercial kitchen and security specifications. For many e-liquid manufacturers, this will be cost prohibitive or otherwise commercially unviable. As a result, manufacturers will have no choice but to stop selling e-liquid in the state.

67. As the vast majority of e-liquid manufacturers, including the Coalition's members, are located outside of Indiana, the burdens imposed by the statute will fall disproportionately on out-of-state manufacturers and on interstate commerce. The Indiana statute will substantially impede the flow of e-liquid into Indiana.

68. The putative local benefits, on the other hand, are relatively few. To begin, it is important to note that the statute does not address many sources of potential adulteration or contamination that could theoretically put consumers at risk. In particular, the commercial kitchen standards only target two discrete issues – the contamination of manufacturing equipment and intentional sabotage or tampering. But neither addresses suppliers who provide contaminated or spoiled ingredients; nor do they do anything to prevent human viruses from directly contaminating an e-liquid solution (*e.g.*, coughing employee). And, of course, to the extent that any of these risks do exist (which the Coalition does not concede), the statute does nothing to protect e-liquid that is manufactured for use in closed systems. Moreover, it is unlikely that e-liquids could become adulterated or contaminated with bacteria or microorganisms that could lead to the types of foodborne illnesses that are the focus of the commercial kitchen code. E-liquids are not manufactured using food and, in fact, contain ingredients that have antimicrobial properties which have been used in the past in hospitals and other settings requiring sterilization.

69. Finally, the statute actually hurts the Indiana consumer. Indiana citizens who vape, including those that look to e-vapor devices as a way to reduce their dependence on traditional cigarettes, will at a minimum have fewer options and potentially lower quality e-liquids being sold by retailers if the e-liquid industry exits the Indiana market.

70. The burdens imposed by the kitchen and security provisions far outweigh the putative local benefits. Under a *Pike* balancing approach, these requirements are unconstitutional and should be set aside as unlawful.

COUNT FOUR

Violation of Equal Protection Clause
Open vs. Closed Systems

71. Petitioner reasserts and incorporates by reference each of the above paragraphs.

72. The Equal Protection Clause of the Fourteenth Amendment prohibits states from regulating similarly situated persons differently where there is no rational relationship between the disparity in treatment and a legitimate state interest.

73. The stated purpose of Indiana's statute and, in particular the objective underlying the commercial kitchen standards and high level security requirements, is to ensure that "e-liquid is not contaminated or adulterated by the inclusion of ingredients or other substances that might pose unreasonable threats to public health or safety" (7.1-7-1-1).

74. HEA 1432, however, only regulates manufacturers of e-liquids used in open systems (or "vapor pens") – *i.e.*, refillable devices. The statute does not impose commercial kitchen or independent security firm obligations on manufacturers of e-liquids used in closed systems (or "electronic cigarettes") – *i.e.*, pre-filled and non-refillable devices (7.1-7-2-10). Moreover, Indiana only requires in-state retailers of e-liquids sold for open devices to ensure that their suppliers have complied with the commercial kitchen and security standards, and only

obligates distributors and retailers of such products deemed to be "tobacco products" to obtain licenses and certifications to operate. Entities dealing in closed systems are exempt.

75. Indiana draws this distinction despite the fact that e-liquids used in both open and closed devices are the same. Those substances are made out of the identical four ingredients (*i.e.*, vegetable glycerin, propylene glycol, flavorings, and liquid nicotine). In fact, some e-liquid manufacturers actually produce and sell the same e-liquids for both types of devices. As such, there is no material difference in the composition of e-liquids used in either system.

76. Not surprisingly, neither HEA 1432 nor SEA 463 articulate any rationale for regulating only those e-liquids used in open systems. Given that e-liquids contain the same ingredients, there is no evidence that e-liquids going into closed systems are any less prone to bacteria or microorganisms that could lead to foodborne illness or are otherwise less likely to be contaminated. Moreover, to the extent that manufacturers of closed systems make their own e-liquids, there is no evidence that they already comply with Indiana's commercial kitchen code and independent security firm measures. In short, to the extent there is any risk of adulteration, contamination, or sabotage, open and closed systems are on equal footing.

77. Because there is no rational basis for regulating only those e-liquids going into open systems while granting immunity to similarly situated closed systems, the statute violates the Equal Protection Clause and, therefore, the commercial kitchen, security, and audit requirements are invalid and should be enjoined.

COUNT FIVE

Violation of Indiana Constitution
Open vs. Closed Systems

78. Petitioner reasserts and incorporates by reference each of the above paragraphs.

79. The Indiana Constitution, Article I, Section 23, prohibits the General Assembly from granting to one citizen or class of citizens any privilege or immunity which, upon the same terms, shall not belong to all citizens.

80. This has been interpreted by the Supreme Court of the State of Indiana to mean that the Indiana General Assembly shall not pass a statute that results in disparate treatment except where there are inherent characteristics distinguishing two classes.

81. This has further been interpreted by the Supreme Court to mean that the preferential treatment must be uniformly applicable to all who are similarly situated.

82. Because e-liquids, regardless of whether they are intended for open or closed devices, are made out of the same ingredients, and because some manufacturers actually sell the same e-liquid for use in open and closed systems, all manufacturers are therefore indistinguishable and are comprised of a common class of citizens. There are no inherent characteristics that are material to distinguishing between open and closed systems for purposes of protecting against the adulteration or contamination of e-liquids sold in Indiana.

83. Retailers and distributors selling e-liquids, whether in Indiana or over the internet, are also regulated only to the extent that they deal in e-liquids for open devices.

84. Accordingly, the statute violates the Indiana Constitution and, thus, the commercial kitchen, security, and audit requirements should be declared invalid and enjoined.

COUNT SIX

Violation of Due Process/Equal Protection Clauses And Indiana Constitution Definition of "Tobacco Product" and Distributor/Retailer Licenses and Certificates

85. Petitioner reasserts and incorporates by reference each of the above paragraphs.

86. HEA 1432 defines "tobacco product" to include "e-liquid that contains tobacco." There is no definition, however, of what constitutes "tobacco." Moreover, because e-liquid is

deemed to be a tobacco product, distributors and retailers in Indiana and those selling e-liquid over the internet, must also obtain valid tobacco distributor licenses and sales certificates under Indiana's general tobacco regulations. Accordingly, Indiana is attempting to regulate e-liquid in the same manner as it controls the sale of traditional cigarette products.

87. E-liquids, however, do not contain tobacco. While many, if not most, e-liquids do include nicotine as an ingredient, nicotine is also not tobacco. Nicotine is a naturally-occurring chemical that exists separate and apart from the tobacco plant. It can be synthesized in the laboratory and derived from non-tobacco plants. Indeed, FDA promotes the use of various smoking cessation products that contain nicotine, but does not regulate those as tobacco products under federal law. Therefore, it is completely arbitrary and in violation of the due process clause to regulate e-liquids as tobacco products under the Indiana statute.

88. Moreover, given that nicotine is not tobacco and that e-liquids otherwise do not contain tobacco, distributors and retailers will not be able discern how Indiana defines "tobacco" under the statute. Indeed, other Indiana statutes appear to define the term to include only those products that traditionally have been understood to contain tobacco leaf or plant (*e.g.,* chewing tobacco, cigars, cigarettes, and pipe tobacco (6-2.5-1-28)). As a result, Indiana's use of the word "tobacco" in the e-liquid statute should be deemed void for vagueness. Otherwise, distributors and retailers will not reasonably know when their products will be considered as containing tobacco and therefore be subject to regulation under state law.

89. Finally, regardless of whether the meaning of "tobacco product" or "tobacco" is vague as employed under the statute, only those distributors and retailers who sell e-liquid for open systems are subject to license and certification requirements. For the reasons stated above, this distinction violates both the Equal Protection Clause and the Indiana Constitution.

90. Indiana's regulation of e-liquid as a "tobacco product" and the associated distributor and retailer requirements should, therefore, be declared unconstitutional and enjoined.

Request For Relief

Wherefore, Intervenor-Petitioner respectfully requests the following relief:

A. A declaration that the commercial kitchen, security, and audit requirements as applied to e-liquid manufacturers and retailers outside Indiana violate the Commerce Clause by virtue of regulating such entities extraterritorially and are unconstitutional.

B. A declaration that the security requirements violate the Due Process Clause and are unconstitutional.

C. A declaration that the commercial kitchen and security requirements violate the Commerce Clause because the burdens imposed on interstate commerce are clearly excessive in relation to the putative benefits and are unconstitutional.

D. A declaration that the commercial kitchen, security, and audit requirements violate the Equal Protection Clause and are unconstitutional.

E. A declaration that the commercial kitchen, security, and audit requirements violate the Indiana Constitution and are unconstitutional.

F. A declaration that the definition of "tobacco product" and the related distributor and retailer requirements violate the Equal Protection and Due Process Clauses and are, therefore, unconstitutional.

G. A preliminary and permanent injunction which restrains and enjoins the Respondents from enforcing the challenged provisions of HEA 1432 and SEA 463.

H. A preliminary injunction which stays the effective date of the challenged provisions of HEA 1432 and SEA 463 until FDA issues the Deeming Regulation and any actions regarding preemption have been fully litigated and resolved.

I. An award of costs and expenses, including attorneys' fees, against the Respondents pursuant to 42 U.S.C. § 1988.

J. Any other relief that the Court deems appropriate.

Date: September 18, 2015

Respectfully submitted,

/s/ Robert D. Epstein
Robert D. Epstein, Atty #6726-49
EPSTEIN COHEN SEIF & PORTER, LLP
50 S. Meridian St., Suite 505
Indianapolis, IN 46204
Telephone (317) 639-1326
Facsimile (317) 638-9891
rdepstein@aol.com

Counsel for Intervenor-Petitioner

Of Counsel and Counsel for Intervenor-Petitioner

Eric P. Gotting (pro hac vice application pending)
Manesh K. Rath (pro hac vice application pending)
Azim Chowdhury (pro hac vice application pending)
KELLER AND HECKMAN LLP
1001 G Street, N.W., Suite 500 West
Washington, D.C. 20001
Telephone (202) 434-4100
Facsimile (202) 434-4646
gotting@khlaw.com

CERTIFICATE OF SERVICE

I hereby certify that on September 18, 2015 a copy of the foregoing document was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

/s Robert D. Epstein
Robert D. Epstein, Atty #6726-49
EPSTEIN COHEN SEIF & PORTER, LLP
50 S. Meridian St., Suite 505
Indianapolis, IN 46204
Telephone (317) 639-1326
Facsimile (317) 638-9891
rdepstein@aol.com