No. 20-1203

In the Supreme Court of the United States

MOOSE JOOCE, et al.,
*Petitioner*s,

v.

FOOD & DRUG ADMINISTRATION, et al.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF OF 36 NATIONAL AND STATE ELECTRONIC NICOTINE DELIVERY SYSTEM PRODUCT ADVOCACY ASSOCIATIONS AND REPRESENTATIVE INDUSTRY STAKEHOLDERS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

J. GREGORY TROUTMAN
Counsel of Record
TROUTMAN LAW OFFICE, PLLC
4205 Springhurst Boulevard,
Suite 201
Louisville, KY 40241
(502) 412-9179
jgtatty@yahoo.com

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GLOSSARY

ACP	Associate Commissioner for Policy
APA	Administrative Procedures Act
ENDS	Electronic Nicotine Delivery System
FDA	Food and Drug Administration
FDCA	Food, Drug and Cosmetic Act
HHS	Department of Health and Human Services
TCA	Family Smoking Prevention and Tobacco Control Act

INTEREST OF THE *AMICI CURIAE*[1]

The *Amici Curiae* are 36 federal or state Electronic Nicotine Delivery System (ENDS) product advocacy associations and representative manufacturing, distribution and retail sector stakeholders.[2] They all have a common mission: advocating for a reasonably regulated marketplace; providing smoke-free alternative products to adult smokers; promoting a positive industry image; and educating elected officials, policymakers and the public regarding ENDS products.

The regulatory regime to which the *Amici* are subjected is of critical importance as the ramifications thereof affect their businesses and advocacy efforts. The *Amici* thus have an overarching interest in ensuring the regulations to which they are subjected pass constitutional muster.

SUMMARY OF THE ARGUMENT

This case concerns the constitutionality of what is colloquially known as the "Deeming Rule".[3] The U.S. Food and Drug Administration

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici curiae* states that no counsel for a party authored this brief in whole or in part or made a monetary contribution toward its preparation. Pursuant to Supreme Court Rule 37.2, counsel for *amici curiae* state that Petitioners and Respondent have all articulated their consent to the filing of the subject *amici curiae* brief.

[2] The names of all *Amici* are listed in Appendix A.

[3] U.S. Food & Drug Admin., *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of*

(FDA) promulgated the Deeming Rule under authority granted by the Family Smoking Protection and Tobacco Control Act (TCA), Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as 21 U.S.C. §§ 387, *et seq*.). The questions at issue here closely parallel those in Case Number 20-850 which is presently pending before the Court.[4]

Congress enacted the TCA to grant the Secretary (Secretary) of the Department of Health and Human Services (HHS) the authority to regulate "tobacco products." Congress defined such term in TCA § 101(a), 123 Stat at 1783 (codified as 21 U.S.C. § 321(rr)(1). It then narrowly applied such definition in Section 901(b) to subject only a subset of products, excluding ENDS products, to immediate regulation. Congress granted the Secretary authority in Section 901(b) to "deem" by regulation all other tobacco products as subject to the TCA's requirements.

In May 2016, the FDA, acting through its Associate Commissioner for Policy (ACP), invoked the deeming authority with respect to all remaining tobacco products. The FDA acted as the Secretary's delegee by virtue of an inter-agency action. The FDA Commissioner sub-delegated the deeming authority to the ACP through an inter-agency

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Tobacco Products and Required Warning Statements for Tobacco Products, 81 FED. REG. 28,974 (May 10, 2016) (codified at 21 C.F.R. § 1143.1).

[4] Case No. 20-850 questions whether the deeming provision set forth in TCA § 901(b), codified as 21 U.S.C. § 387a(b), violates the Separation of Powers doctrine embodied in U.S. CONST., art. I, sec. 1.

action. The ACP is a permanent FDA position but does not require a presidential appointment and Senate confirmation.

First, the *Amici* herein recite the recent history of the regulation of tobacco products, both the brief history of ENDS products, and the federal efforts to regulate them. This history frames the context of the issues before the Court.

Second, the *Amici* assert the Deeming Rule is unconstitutional because the FDA violated the Appointments Clause of the United States Constitution, U.S. CONST, art. II, § 2, cl. 2, by sub-delegating its deeming authority to an agency official who lacks rulemaking powers. The TCA vested the Secretary with deeming authority. The Secretary delegated such authority to the FDA Commissioner who sub-delegated the authority to the agency's ACP. Yet, the ACP is not an "Officer of the United States" according to *Buckley v. Valeo*, 424 U.S. 1 (1976). *Buckley* dictates that only Officers of the United States have rulemaking authority. Instead, the ACP holds an inferior office, and thus lacks the requisite legal authority to implement regulations which have the force of law.

Finally, the *Amici* address the circuit court's finding that a former FDA Commissioner ratified the Deeming Rule. Such finding was flawed because: (1) the Deeming Rule was incapable of ratification as the Section 901(b) deeming authority is itself unconstitutional; (2) the attempted ratifications violated the Administrative Procedures Act's notice requirements; and (3) the FDA's attempted ratifications were ineffective in substance given

both the changes of circumstances occurring in the interim and the agency's structural changes to the Deeming Rule.

ARGUMENT

I. Background history of tobacco regulation and ENDS products.

Understanding the recent history of the federal regulation of tobacco products and ENDS products is necessary to contextualize the unconstitutionality of the manner in which the FDA promulgated the Deeming Rule.

A. Regulation of tobacco products.

Until the early years of this century, a "tobacco product" was something a person either ignited and inhaled, chewed, or placed between the cheek and gum. Numerous federal regulatory efforts repeatedly failed for a myriad of reasons although the dangers of the products were unquestioned.

The FDA got tired of waiting. In August 1996, it issued a regulation which asserted authority over tobacco products. It classified nicotine as a "drug" under the Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq*., and cigarettes and smokeless tobacco as "combination products" that deliver nicotine to the body. 61 FED. REG. 44,619 – 45,318 (1996).

In March 2000, this Court's opinion in *FDA v. Brown & Williamson Tobacco Corp.,* 529 U.S. 120 (2000) upheld the striking down of the FDA's regulation. Therein, the Court held the FDA exceeded its authority under the FDCA because Congress

had not authorized it to either classify nicotine as a drug or independently regulate tobacco products. *Id*. at 142.

B. History of ENDS products.

Contrary to a common public perception, the legacy tobacco companies did not invent ENDS products. They instead have a far humbler origin. In 2003, a Chinese pharmacist, Mr. Hon Lik, developed the first marketable[5] ENDS product which employed a piezoelectric element to vaporize a liquid nicotine and propylene glycol solution.[6] Mr. Hon sought a safer way to inhale nicotine as a smoking cessation alternative in response to his father, a smoker, dying from lung cancer.[7]

ENDS products do not contain any part of a tobacco leaf or stalk. Their use does not involve combustion or the emission of the many toxic substances associated with smoking. They instead utilize a liquid solution of propylene glycol, vegetable glycerin, food-grade flavorings, and in some cases, nicotine of varying concentrations. Such nicotine is derived either from tobacco plants, another plant (*i.e*. tomatoes, potatoes, celery, cauliflower, peppers or eggplant), or made synthetically.

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[5] The first patented ENDS product was developed in the early 1960's but never marketed.

[6] Nguyen, *et al.*, Electronic Cigarettes the Past, Present and Future (The History of E-cigarettes). Available at https://www.dentalcare.com/en-us/profesional-education/ce-courses/ce451/the-history-of-e-cigarettes. (Accessed March 26, 2021).

[7] *Id*.

In 2004, Mr. Hon introduced his ENDS product to the Chinese market. The success of Mr. Hon's product soon resulted in worldwide marketing and sales.[8] ENDS products first came to the United States in 2007. The initial American market participants were non-tobacco companies solely devoted to the manufacturer and sale of ENDS products.[9] Legacy tobacco companies did not enter the ENDS products market until around 2012, after the products were well established in the United States.

American entrepreneurialism soon resulted in the establishment of thousands of small domestic ENDS product manufacturers, distributors and retailers. These industry stakeholders, not affiliated with the legacy tobacco companies, drove significant market innovations by improving product quality and consistency.[10] By 2018, the United States ENDS product market had grown to $4.2 billion dollars and is expected to have a compound annual growth rate of 24.1% from 2019 to 2025.[11] This increase in ENDS product use among American adult smokers draws a strong correlation to

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[8] Nguyen, *supra*.

[9] *Id.*

[10] A Billion Lives (Attention Era Media 2016) at 30:13 to 37:20. https://tubitv.com/movies/499729/a-billion-lives.

[11] https://www.grandviewresearch.com/industry-analysis/us-e-cigarette-vapemarket#:~:text=The%20U.S.%20e%2Dcigrette%20and,24.1%25%20from%202019%20to%202025.&text=As%20a%20result%2C%20e%2Dcigarette,alternatives%20to%20conventional%20tobacco%20cigarettes./ (Accessed March 26, 2021).

the statistically significant decrease in the nation's smoking rate.[12]

C. ENDS market segmentation.

ENDS products industry stakeholders have segregated themselves into two distinctive market segments: the "open system" and "closed system" segments. This segmentation tracks the character of the product manufacturers (large corporations versus closely-held businesses), the products' physical characteristics and the products' retail channels.

1. Closed system ENDS products.

Closed system products are generally manufactured and distributed by legacy tobacco companies such as Reynolds American (*VUSE*® brand) and Imperial Brands (*Blu*® brand). The most popular of such products, by market share, is the *Juul*® brand which is manufactured and distributed by Juul Labs, Inc.[13] Closed system products comprised approximately 58% of the nation's total ENDS products market as of 2018.[14]

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[12] Shu-Hong Zhu, *et al.*, E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. BMJ, 2017; j3262 DOI: 10.1136/bmj.j3262.

[13] In late 2018, legacy tobacco company Altria Group purchased a 35% share of Juul Labs for approximately $13 billion dollars.

[14] See Bonnie Herzog, Nielsen: Tobacco All Channel Data Through 9/8, WELLS FARGO SECURITIES, (Sept. 8, 2018).

Closed-system products have two distinguishing features: (1) small device size and (2) a disposable pre-filled cartridge or pod which offers e-liquid in a limited variety of flavor choices. The batteries used in closed-system devices generate a low capacity of power and thus require e-liquids with a high nicotine concentration[15] in order to provide a satisfactory consumer experience. Many closed system e-liquids have a nicotine concentration of 50 mg/ml or higher, equivalent to the nicotine contained in a pack of cigarettes.[16] These products allow consumers few customization options. Appendix B hereto depicts photographs of representative examples of closed system products.

2. Open system ENDS products.

The birth and growth of the open system segment can be traced to an early 2010's grassroots movement of consumers who were dissatisfied with the quality of early closed system products. In particular, these consumers were dissatisfied with the low power of such devices and poor quality of e-liquids. This grassroots movement resulted in the development of open system devices and components. It also resulted in the creation of numerous manufacturers, distributors, and retailers for these new products.

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[15] The nicotine content of all e-liquids used in ENDS products is measured in milligrams per milliliter.

[16] A closed system pod will generally range in size from .5 ml to 1ml. In many instances the nicotine concentration of a pod will approximate 5% of the total liquid volume.

Open system devices are typically larger in size than closed system devices. They rely on three key elements: (1) higher-powered, rechargeable lithium batteries which are either replaceable or self-contained within the device; (2) computer circuitry which allows the independent regulation of both the device thermal and wattage parameters; and (3) interchangeable and refillable e-liquid tanks (referred to as atomizers). These advances have allowed consumers virtually unlimited freedom to personally customize their devices.

In conjunction with the advent of open system devices, consumers also attempted to create higher quality e-liquid products for their personal use. This resulted in the creation of thousands of open system e-liquid brands and flavors. Open system devices generate a greater quantity of power *vis-à-vis* their closed system counterparts. Thus, open system devices generally require e-liquids which contain a lower nicotine concentration. Open system e-liquids typically contain nicotine in varying concentrations at 3 mg/ml increments ranging from 0 mg/ml to 12 mg/ml.

What began as experimentation by consumers has evolved into large scale manufacturing operations now conducted in certified labs and clean rooms. The result has been a consumer-driven phenomena: if an open-system consumer has a particular flavor or taste preference, there are likely multiple product options available to satisfy such preference. Appendix C hereto depicts photographs of representative examples of open system ENDS products.

D. Initial regulation of ENDS products.

In early 2009, the FDA added several Chinese manufactured closed system ENDS products to Import Alert 66-41.[17] This Alert directed U.S. Customs and Border Protection to reject the entry of the products, imported for sale by domestic distributors, as unapproved drug delivery devices.

In April 2009, one of those distributors sued the FDA to enjoin its import ban. The premise of such challenge was that ENDS products were "tobacco products" over which the FDA lacked regulatory authority. In December 2010, the D.C. Circuit upheld the district court's holding that the FDA lacked authority to independently classify ENDS products as a drug or drug/device combination. See *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010).

E. The Tobacco Control Act.

While *Sottera* was pending, Congress enacted the TCA in June 2009. The TCA added a new Chapter IX to the FDCA and granted the Secretary the authority to regulate "tobacco products". Therein, Congress defined such term in relevant part as being:

> "any product made or derived from tobacco that is intended for human

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[17] Import Alert 66-41, *Detention Without Physical Examination of Unapproved New Drugs Promoted in the U.S.*, March 30, 2009 (Shenzen Kanger Technology Co.) and April 6, 2009 (Desonic Industrial and Loongtotem Science and Technology Co.). Available at https://www.accessdata.fda.gov/cms_ia/importalert_190.html. (Accessed March 26, 2021).

> consumption, including any component, part, or accessory...."

TCA § 101. Congress, however, did not subject all tobacco products to the immediate reach of the TCA's various regulatory requirements. Instead, TCA § 901(b) subjected only a limited subset of four product classes to the TCA. [18]

Congress left all other tobacco products which satisfied the TCA § 101 definition outside the TCA's immediate scope. This included cigars, pipe tobacco, hookah and ENDS products. Congress, instead, granted the Secretary the plenary authority to regulate all other tobacco products through a regulatory deeming. TCA § 901(b).

F. The FDA Deeming Rule.

In April 2014, the ACP published a notice of proposed rulemaking in the Federal Register regarding the FDA's anticipated exercise of its deeming authority under the TCA.[19] On May 10, 2016, the ACP published the Deeming Rule in the Federal Register.[20] This Rule applied the TCA's requirements to all other tobacco products (including ENDS products) containing, or intended to be used

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[18] ENDS products which either do not contain nicotine or which contain nicotine derived from a source other than tobacco would ostensibly fall outside the "tobacco products" definition and thus be beyond the FDA's regulatory control.

[19] Proposed Rule, 79 FED. REG. 23141-23207 (April 25, 2014).

[20] Deeming Rule*, supra,* 81 FED. REG. 28,974 – 29,106 (May 10, 2016).

with, nicotine derived from tobacco. 81 FED. REG. at 28,976. The Deeming Rule took effect on August 8, 2016.[21] *Id*., at 28,974.

The question presented here is whether the FDA violated Article II, § 2, cl. 2 of the United States Constitution in permitting the agency's ACP, a position not appointed by the President and confirmed by the Senate, to publish both the notice of proposed rulemaking and Deeming Rule.

II. The FDA violated the Constitution's Appointments Clause when adopting the Deeming Rule.

The Appointments Clause of the Constitution specifies the acceptable manner of filling senior executive- and judicial-branch offices. Such Clause provides that:

> "He [the President] shall have Power, by and with the Advice and Consent of the Senate, to make Treaties, provided two thirds of the Senators present concur; and he shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not

[21] ENDS products fell outside the TCA's "grandfather" provision because none were marketed in the United States as of February 2007. The result creates a logical fiction. There were thousands of ENDS products on the market as of the August 8, 2016 deeming date but they instantly became treated as non-existent. Such products must obtain a Pre-Marketing Tobacco Order from the FDA as if they were new products in order to remain on the market.

> herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments."

U.S. CONST., art. II, § 2, cl. 2. The *Amici* urge the Court to grant certiorari to opine whether the FDA violated the Appointments Clause when promulgating the Deeming Rule.

This Court held in *United States v. Germaine*, 99 U.S. 508, 509-10 (1879) that the Appointments Clause evidences the Framers' intention to create two classes of officers: (1) Officers of the United States which require nomination by the President and confirmation by the Senate and (2) all other inferior Officers which Congress vested the authority of appointment in the President, the courts of law, or the heads of departments.

This Court's landmark opinion in *Buckley, supra* at 126, held the term "Officers of the United States" means "all persons who can be said to hold an office under the government," citing *Germaine*, *supra* at 510. Accordingly, this Court held that an Officer of the United States is "any appointee exercising significant authority pursuant to the laws of the United States". 424 U.S. at 126. Such officers must, therefore, be appointed in the manner prescribed by the Appointments Clause. *Id.*

On the other hand, this Court held in *Edmond v. United States*, 520 U.S. 651, 662 (1997) that an "inferior officer" occupies a position which

connotes a relationship with some higher ranking officer or officers below the President. "Whether one is an 'inferior' officer depends on whether he has a superior." *Id*. The FDA's organizational chart shows the ACP has a superior, an FDA Deputy Commissioner.[22]

In drawing the line between principal and inferior officers, this Court determined in *Buckley* that rulemaking power is deemed significant federal authority and thus reserved solely to Officers of the United States. *Buckley*, *supra*. at 126, 140–41. This Court deemed such rulemaking authority as a significant function for Appointments Clause purposes because the effects thereof "alter[] the legal rights, duties and relations" of private parties and government actors. *INS v. Chadha*, 462 U.S. 919, 952 (1983). Thus, *Buckley* results in the following tautology: The Appointments Clause vests Officers of the United States with significant authority; agency rulemaking is a significant authority; therefore agency rulemaking must be conducted only by persons who are Officers of the United States.

In the context of the Deeming Rule, the Secretary and FDA Commissioner are both Officers of the United States under the Appointments Clause. They each accordingly hold office by virtue of a presidential nomination and Senate confirmation. The ACP, however, is an inferior officer. The ACP position is appointed by a department head and is

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[22] *See* https://www.fda.gov/about-fda/fda-organization-charts/fda-overview-organization-chart. (Accessed March 26, 2021).

therefore authorized to only exercise the duties of such inferior office. These duties do not include rulemaking authority as *Buckley* dictates that such agency function is reserved only to principal officers who have undergone the constitutional appointment and confirmation process. Following the aforementioned tautology, the ACP lacks the constitutional authority to engage in rulemaking on the FDA's behalf as an inferior officer. This lack of authority would necessarily include duties such as publishing notices of proposed rulemaking which set the regulatory process in motion.

The issues of the FDA's internal rulemaking policies are the tip of the proverbial iceberg. The Secretary has maintained a practice within HHS of delegating authority to the FDA Commissioner which dates back almost 50 years.[23] This has created:

> "[a]n unbroken practice of deference to the FDA [which] seemed to have developed at the HHS level," so much so that the "practice had hardened into a convention."[24]

The FDA's internal practice of sub-delegating significant authority to inferior officers is also long standing. For many years, the FDA has sub-delegated full rulemaking authority to the ACP arising under both the FDCA and the TCA. *See* FDA Staff Manual § 1410.10(1)(A)(1) which authorizes the

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[23] Commissioner of Food and Drugs, 38 FED. REG. 6668, 6668–69 (Mar. 12, 1973) (codified at 21 C.F.R. pt. 2).

[24] Adrian Vermeule, Conventions of Agency Independence, 113 Colum. L. Rev. 1163, 1208 (2013).

ACP to assume the FDA Commissioner's authority to issue "proposed and final regulations of the Food and Drug Administration".

The FDA's Staff Manual also vests the ACP with almost unbridled plenary authority to make substantive and procedural determinations in support of the subject rulemaking authority. *See* FDA Staff Manual § 1410.21. This allows the ACP to make predicate factual determinations required by an enabling statute as part of the rulemaking process.[25]

The ACP has this broad authority but was never appointed by a president nor confirmed by the Senate. The ACP thus exercises the functions of an Officer of the United States without satisfying the requisite requirements. As such, the ACP bears no direct accountability to the Americans whose lives are affected by the edicts he or she issues. This Court should consider the totality of the scope of the ACP's authority in conducting an Appointments Clause analysis. *See Freytag v. C.I.R.*, 501 U.S. 868, 882 (1991).

In this instance, the ACP published the notice of proposed rulemaking and promulgated the Deeming Rule pursuant to aforementioned delegated authority.[26] The ACP thus exercised

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[25] The FDA Staff Manual does not articulate what, if any, coordination or consultation the ACP must have with principal officers when undertaking rulemaking functions on the agency's behalf.

[26] *See* Deeming Rule, 81 FED. REG. at 28,982 (citing statutory authority for issuance of the Rule, including 21 U.S.C.

"significant authority pursuant to the laws of the United States". The circuit court's analysis was flawed because an inferior officer, like the ACP, lacks the legal authority under the Appointments Clause to enact rules and regulations which have the force of law. The FDA's long-standing practice of deferring rulemaking authority to inferior officers is contrary to the Appointments Clause. The Court should grant certiorari to address the constitutionality of the FDA's policy of internal agency delegation of rulemaking authority to its inferior officers.

III. The FDA's attempts to later ratify the Deeming Rule were procedurally defective.

The circuit court primarily focused its opinion upon the efficacy of the attempts by a former FDA Commissioner to ratify the Deeming Rule. The circuit court's finding of a valid ratification is contrary to both fact and law. There are two fundamental fatal flaws inherent in the ratification finding.

The first fatal flaw is the fact the deeming authority granted by TCA § 901(b) is itself unconstitutional on Separation of Powers grounds. The petitioners and industry *amici curiae* in Case 20-850 thoroughly discussed the Separation of Powers defect inherent in TCA § 901(b). The FDA's attempted ratifications of the Deeming Rule failed to cure this fundamental organic defect. The Deeming Rule was unconstitutional prior to the

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§§ 371(a), 387a); *id.* at 29,016 (identifying the ACP as the sole issuer of the Rule).

attempted ratifications and thus incapable of being ratified.

The second fatal flaw is the fact former FDA Commissioners attempted to ratify a prior agency action which was not capable of ratification on Administrative Procedures Act grounds. This Court's ratification jurisprudence dictates that:

> "the party ratifying should be able not merely to do the act ratified at the time the act was done, *but also at the time the ratification was made*."

FEC v. NRA Political Victory Fund, 513 U.S. 88, 98 (1994) (internal quotations marks and citation omitted, emphasis in original).

A ratification could not occur in this instance for the simple reason that neither former FDA Commissioner was attempting to ratify an otherwise valid regulatory enactment. In other words, they were not merely attempting to correct a technical defect but instead an organic defect. This is the case because of the FDA's initial failure to comply with Section 553 of the Administrative Procedures Act (APA), 80 Stat. 383-84 (codified as 5 U.S.C. § 553), when attempting to promulgate the Rule.

Section 553 requires that federal agencies publish a notice of proposed substantive rulemaking and allow a period of public comment. Here, the ACP published the notice of proposed rulemaking for the Deeming Rule in the Federal Register in

April 2014.[27] Yet, in light of *Buckley, supra,* the ACP arguably lacked the constitutional authority as an inferior officer to issue the subject notice because she lacked any rulemaking authority. This would arguably negate the validity of the Deeming Rule's notice of proposed rulemaking. As a result, the Deeming Rule never satisfied the APA's predicate requirements. An agency's failure to satisfy such requirements during the rulemaking process nullifies its actions. See *Amer. Acad. of Pediatrics v. FDA*, 379 F.Supp.3d 461, 498 (D.Md. 2019). The FDA knows that fact all too well when it comes to the Deeming Rule.

The FDA's attempted ratifications did not recite an intention to cure the defective publication of the Deeming Rule's notice of proposed rulemaking. This Court in *NRA Political Victory Fund, supra.* rejected the assertion that a ratification related back in time to cure a prior procedural defect. Just as the Solicitor General's belated ratification effort was ineffective to cure a prior procedural defect in *NRA Political Victory Fund*, the attempted ratifications were ineffective in this instance to cure the ACP's defective publication of the notice of proposed rulemaking.

IV. The substance of the FDA's ratification attempts were ineffective.

On the merits, the attempts of the two former FDA Commissioners to ratify the Deeming Rule were ineffective. This is the case because the circumstances underlying the Deeming Rule had

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[27] Proposed Rule, 79 FED. REG. 23141-23207 (April 25, 2014).

changed between the time of its May 2016 publication and the attempted ratifications.

The FDA acknowledged in the Deeming Rule that the science underlying the public health impact of ENDS products was far from settled.[28] Scientific inquiry, however, did not stop evolving after publication of the Deeming Rule. The record below does not indicate that the FDA considered either this evolution, or its intervening structural changes to the Deeming Rule, when attempting a ratification. Such ratification attempts were thus contrary to the APA's requirement of reasoned decision making, and thus invalid, in the absence of such proof.

1. Califf ratification.

On September 21, 2016, then-FDA Commissioner Dr. Robert Califf issued a nine page Memorandum.[29]/[30] Therein, Dr. Califf confirmed the

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[28] *See* 81 FED. REG. at 29,010.

[29] U.S. Food & Drug Admin., *Delegation of Authority for General Redelegations of Authority from the Commissioner to Other Officers of the Food and Drug Administration* (Sept. 21, 2016).

[30] The FDA did not publish the Califf Memorandum in the Federal Register. Apparently, such publication is not required in the DC Circuit. See *Alfa Int'l Seafood v. Ross*, 264 F. Supp. 3d 23 (D.D.C. 2017). Other federal decisions, however, have noted the filing of ratification instruments in the Federal Register by agencies. *See e.g. State Nat'l Bank of Big Spring v. Lew*, 197 F. Supp. 3d 177 (D.D.C. 2016) [Consumer Financial Protection Bureau] and *South Dakota vs. U.S. Dept. of Interior*, 314 F. Supp. 2d 935 (D.S.D. 2004) [Department of Interior]. *Amici* ponder whether Section 553

redelegation of authority in accordance the Section 1410 of the FDA's Staff Manual with respect to the duties of eight specific agency officials. Dr. Califf empowered those officials to perform the Commissioner's delegable functions and further delineated the scope of such authority.

The FDA's Deputy Commissioner for Policy, Planning, Legislation and Analysis, under which the ACP operates, was among the eight agency officials included within the scope of the Califf Memorandum. Dr. Califf did not specifically refer to the Deeming Rule in his Memorandum, but did generally state:

> "In addition, I hereby ratify and affirm any actions taken by you or your subordinate(s), which in effect involved the exercise of the authorities delegated herein prior to the effective date of this delegation."

Califf Memorandum, sec. 3(B). *See* Petition App. G-16. Ostensibly, Dr. Califf intended this ratification to encompass the ACP's actions taken under the TCA.

Established principles of administrative law require that agencies undertake reasoned decision making. *Allentown Mack Sales & Serv. v. NLRB*, 522 U.S. 359, 374 (1988). This required that Dr. Califf consider any new information, like scientific studies, regarding the matter being regulated. *See Butte County v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010) [an agency's refusal to consider evidence bearing on the issue before it constitutes an

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of the APA required such a filing.

arbitrary action]. The Califf ratification was contrary to the APA because it failed to articulate any reasoned basis for the subject action, including the consideration of new information.

The administrative record was closed at the time of the Califf ratification. The circuit court thus held that *Hogen* only required an agency to consider new information when the administrative record is still open. The court, however, did not point to an analogous case which excused an agency's failure to consider subsequent facts when attempting to ratify a regulation after the close of the administrative record.

It begs the question how the Califf ratification could have resulted from reasoned decision making absent any statement detailing what facts he considered. This absence is important because scientific inquiry did not cease during the interim between the Deeming Rule's promulgation and the Califf ratification. Appendix C hereto sets forth a survey of pertinent studies published in that interim period which would have been a part of any reasoned process when contemplating a ratification. The record below is bereft of any evidence that Dr. Califf considered any of these pertinent studies when contemplating a ratification.[31] One can only speculate whether Dr. Califf considered

[31] Dr. Califf and his successor, Dr. Scott Gottlieb, were not deposed in the proceedings below. Further, the FDA did not submit an affidavit in the proceedings below from either Dr. Califf or Dr. Gottlieb which articulated the scope of their specific inquiries when attempting the respective ratifications.

any of the subsequent studies in calculating his ratification.

2. Gottlieb Ratification.

In April 2019, shortly before his departure, then-FDA Commissioner Dr. Scott Gottlieb issued a second attempted ratification of the Deeming Rule. The purported Gottlieb ratification recited the fact that the FDA published the Deeming Rule in May 2016 and then acknowledged the subject legal challenge regarding the validity of its adoption. The four corners of Dr. Gottlieb's purported ratification then stated:

> "I hereby affirm and ratify the Deeming Rule *as of the date it was published in the Federal Register on May 10, 2016*, including all regulatory analysis certifications contained therein." (Emphasis added).

Dr. Gottlieb plainly stated his intention was to resolve questions about the legitimacy of the Deeming Rule's enactment.

Like the Califf Memorandum, the FDA did not publish the Gottlieb ratification in the Federal Register. There is also an absence of proof in the record below that the Gottlieb ratification document was the result of reasoned decision making.

Dr. Gottlieb plainly articulated that he was undertaking an attempted ratification:

> "based on [his] careful review of the rule, [his] knowledge of its provisions, and [his] close involvement in policy matters

> relating to this rule and its implementation, as well as its public health importance."

As was the case with the Califf ratification, additional relevant studies were published between September 2016 and April 2019. Further, the FDA made structural changes to the Deeming Rule in the interim which resulted in it differing significantly from the rule adopted in May 2016. The record below, however, is bereft of any proof concerning the scope of Dr. Gottlieb's review, or his consideration, of such matters when contemplating a ratification. One can only speculate whether Dr. Gottlieb considered any of the subsequent studies of changes to the Deeming Rule in calculating his ratification.

a. Agency Changes to Deeming Rule.

The Deeming Rule set forth a series of industry compliance benchmark dates, staggered over a two-year period, with respect to various aspects of the FDA's regulation. These compliance benchmarks required, *inter alia*: initial manufacturer and product registration; ingredient reporting and submission of health information; and the inclusion of nicotine warning labels on products. The FDA set August 8, 2018 (two years from the effective date of filing of a Pre-Market Tobacco Application (PMTA).[32]

Subsequent to May 2016, however, the FDA initiated serial modifications to the Deeming Rule.

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[32] Deeming Rule, 81 FED. REG. at 29,011.

Some of the modifications were due to technology infrastructure inadequacies within the agency, the occurrence of natural disasters,[33] or the agency's recalibration of its regulatory mindset.[34]

For example, in May 2017, the FDA extended all future compliance deadlines by three months.[35] In August 2017, the FDA broadly extended all compliance timelines, including a four year extension for the submission of PMTA applications.[36] In October 2017, the FDA extended the compliance deadlines for ingredient listing and tobacco health document submissions by six months for manufacturers and importers located in certain natural disaster areas.[37] In April 2019, the day before the

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[33] The FDA's underestimation of the number of initial manufacturer and product registrations resulted in multiple crashes of its servers. The FDA also later accounted for business interruptions resulting from natural disasters like Hurricane Harvey.

[34] *See* FDA News Release, FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death (July 27, 2017). https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death (Accessed March 26, 2021).

[35] https://www.fda.gov/tobacco-products/compliance-enforcement-training/effective-and-compliance-dates-applicable-retailers-manufacturers-importers-and-distributors-deemed (Accessed March 26, 2021).

[36] *See* Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry, 82 FED. REG. 37459 (August 10, 2017).

[37] *See* https://www.fda.gov/tobacco-products/ctp-newsroom/fda-actions-regarding-tobacco-manufacturers-

Gottlieb ratification, the FDA revised certain compliance requirements for submissions of Harmful and Potentially Harmful Constituents as part of the preliminary PMTA process.[38] These serial modifications resulted in the final compliance benchmark, the submission of a PMTA being moved from August 2018 to August 2022.

Dr. Gottlieb sought to ratify the Deeming Rule as it was published in May 2016. Yet, the FDA had radically changed the Deeming Rule. The FDA's extension of the PMTA deadline was a foundational modification which a federal court has ruled was "'tantamount to amending or revoking a rule,'" and "amount[ed] to substantive rulemaking subject to the APA's constraints and generally reviewable by courts." *Amer. Acad. of Pediatrics*, *supra* at 481 (internal citations omitted). The FDA is bound by such determination based upon principles of issue preclusion. See *Bravo-Fernandez v. United States*, 580 U.S. ___, 137 S. Ct. 352, 356 (2016).

The record below is bereft of any proof that Dr. Gottlieb conducted "an independent evaluation of the merits," *Intercollegiate Broad. Sys. v. Copyright Royalty Bd. & Librarian of Cong.*, 796 F.3d 111, 117 (D.C. Cir. 2015) which considered the agency's organic changes to the Deeming Rule when calculating his attempted ratification. The circuit's ratification finding was thus erroneous.

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importers-affected-recent-natural-disasters. (Accessed March 26, 2021).

[38] See 84 FED. REG. 12,740 – 12,791 (April 2, 2019).

b. Evolution of Scientific Inquiry.

In this instance, the scientific inquiry about ENDS products had also progressed substantially between the time of the purported Califf ratification and the time of Dr. Gottlieb's ratification attempt. The scientific consensus had congealed more in favor of ENDS products in the interim. Appendix E hereto sets forth a survey of pertinent studies published in the interim between the purported Califf ratification and the Gottlieb ratification. The record below, however, is bereft of any evidence that Dr. Gottlieb considered any of these pertinent studies when contemplating a ratification. His ratification can thus not be considered the result of reasoned decision making.

CONCLUSION

For the above reasons, the *Amici* respectfully ask this Court to grant certiorari to the U.S. Court of Appeals for the District of Columbia Circuit in order to determine whether the Deeming Rule violates the Appointments Clause.

Respectfully submitted,

J. GREGORY TROUTMAN
COUNSEL OF RECORD
TROUTMAN LAW OFFICE, PLLC.
4205 Springhurst Boulevard,
Suite 201
Louisville, KY 40241
(502) 412-9179
jgtatty@yahoo.com
Counsel for *amici curiae*

March 2021

APPENDIX A

NATIONAL ENDS ADVOCACY ORGANIZATIONS

AMERICAN VAPING ASSOCIATION

CONSUMER ADVOCATES FOR SMOKE-FREE ALTERNATIVES ASSOCIATION

SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION

UNITED VAPERS ALLIANCE

STATE ENDS ADVOCACY ORGANIZATIONS

ARIZONA SMOKE FREE BUSINESS ALLIANCE

BREATHE EASY ALLIANCE OF ALABAMA

CONNECTICUT CHAPTER OF SMOKE FREE ALTERNATIVES TRADE ASSOCIATION

FLORIDA SMOKE FREE ASSOCIATION, INC.

GEORGIA SMOKE FREE ASSOCIATION, INC.

HAWAII CHAPTER OF SMOKE FREE ALTERNATIVES TRADE ASSOCIATION

KANSAS SMOKE FREE ASSOCIATION

KENTUCKY VAPING RETAILERS ASSOCIATION, INC., d/b/a KENTUCKY SMOKE FREE ASSOCIATION

INDIANA SMOKE FREE ALLIANCE, INC.

IOWA VAPE ASSOCIATION, INC.

LOUISIANA CHAPTER OF SMOKE FREE ALTERNATIVES TRADE ASSOCIATION

LOUISIANA VAPING ASSOCIATION

MICHIGAN VAPE SHOP OWNERS, INC.

MINNESOTA SMOKE FREE ALLIANCE
MISSOURI SMOKE FREE, INC.
MONTANA SMOKE FREE ASSOCIATION, INC.
NEVADA VAPING ASSOCIATION, INC.
NEW YORK STATE VAPOR ASSOCIATION, INC.
NORTH CAROLINA VAPING COUNCIL, INC.
OHIO VAPOR TRADE ASSOCIATION, INC.
ROCKY MOUNTAIN SMOKE FREE ASSOCIATION, INC.
RHODE ISLAND CHAPTER OF SMOKE FREE ALTERNATIVES TRADE ASSOCIATION
SOUTH CAROLINA VAPOR ASSOCIATION
TEXAS CHAPTER OF SMOKE FREE ALTERNATIVES TRADE ASSOCIATION
VAPOR RETAILERS AND MANUFACTURERS OF DELAWARE
VIRGINIA SMOKE FREE ASSOCIATION, INC.
WASHINGTON SMOKE FREE ASSOCIATION, INC.
WEST VIRGINIA SMOKE FREE ASSOCIATION, INC.

REPRESENTATIVE INDUSTRY MANUFACTURING STAKEHOLDER

GRIPPUM, LLC.
CHICAGO, IL

REPRESENTIVE INDUSTRY DISTRIBUTION STAKEHOLDER

OP MURSE HOLDINGS, LLC.,
d/b/a OPMH PROJECT
LOUISVILLE, KY

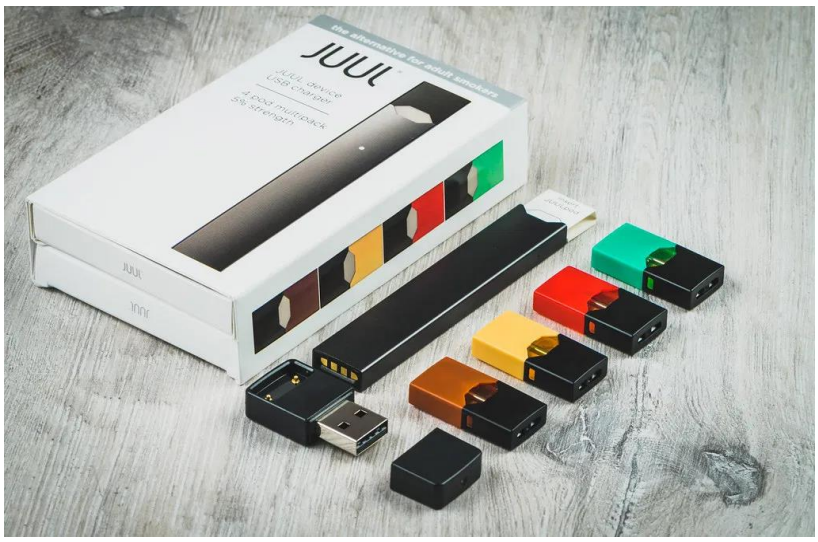
REPRESENTATIVE INDUSTRY RETAIL STAKEHOLDERS

DERBECIGS, LLC.
LOUISVILLE, KY

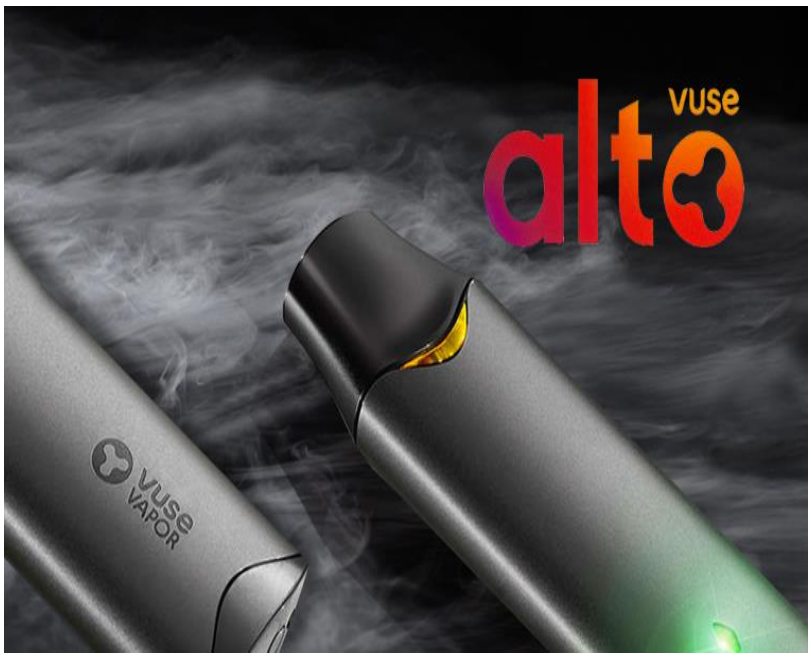
DERBECIGS INDIANA, LLC.
CLARKSVILLE, IN

APPENDIX B

Specimen photographs of
Closed System ENDS products

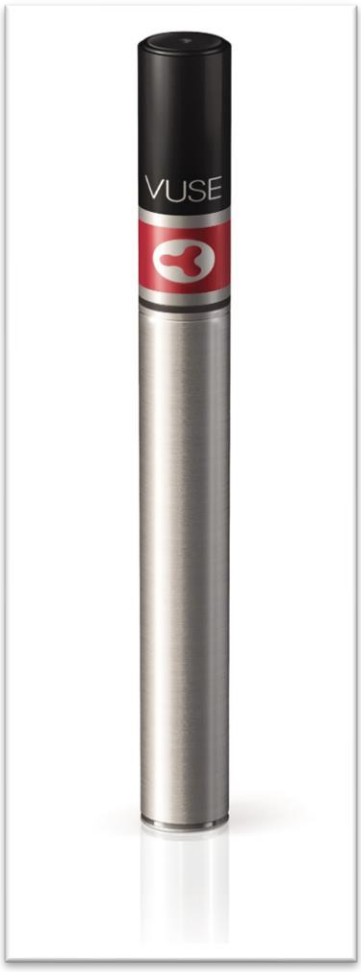


Juul® Device and pods in assorted flavors
Manufactured and distributed by Juul Labs, Inc.



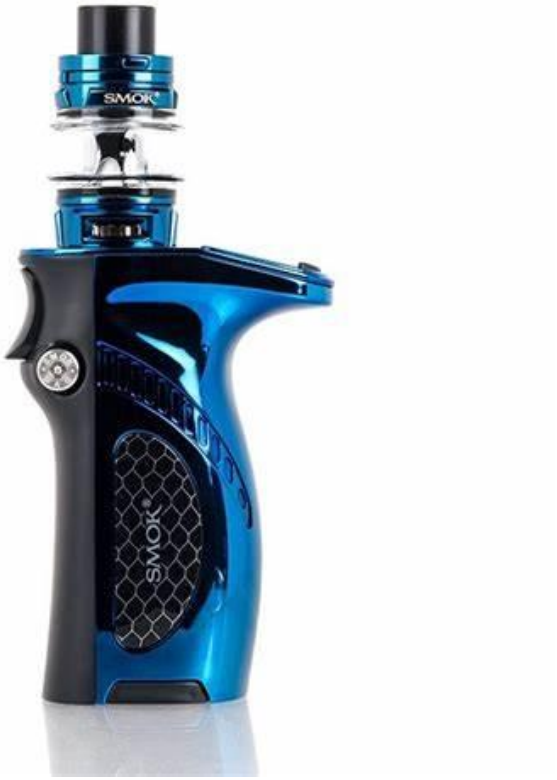
VUSE Alto® device with pod inserted
Manufactured by R.J. Reynolds Vapor Company

A-6



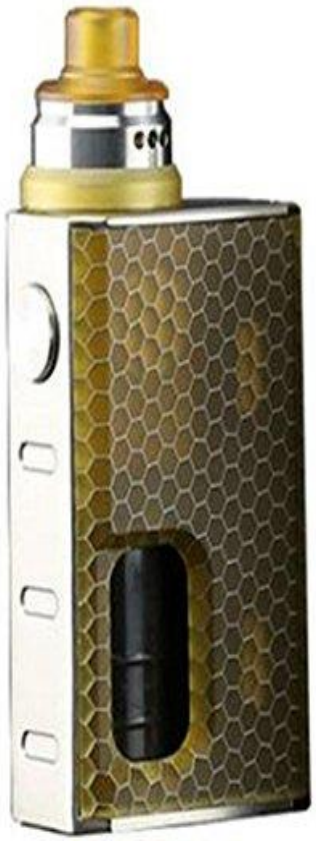
VUSE Solo® device with pod attached
Manufactured by R.J. Reynolds Vapor Company

APPENDIX C
Specimen photographs of
Open System ENDS products



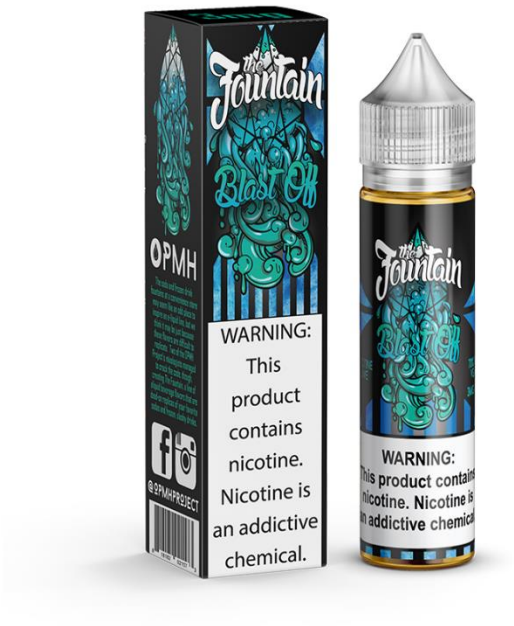
Smok Mag Grip 85W Mod
Manufactured by Shenzhen IVPS
Technology Co Limited

A-8



Wismec Luxotic 100W Squonk Box Mod
Manufactured by Wismec Electronics, Ltd.

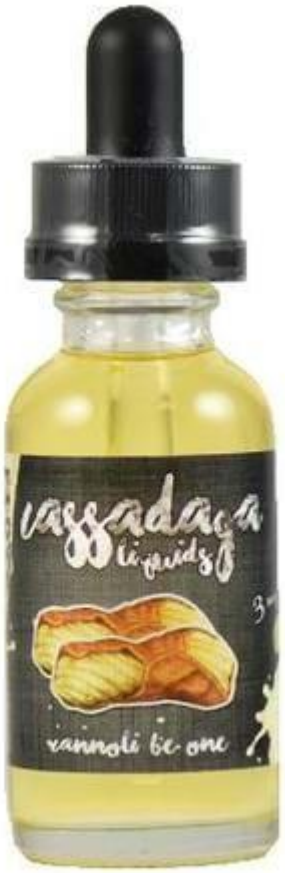
A-9



Fountain *Blast Off* (Blue Tropical Slushy) E-liquid
60ml bottle and 6mg/ml nicotine

Manufactured by Grippum, LLC and
Distributed by OP Murse Holdings, LLC.

A-10



Cannoli Be One (Vanilla cannoli) E-liquid
30ml bottle and 3mg/ml nicotine

Manufactured and Distributed by Cassadaga Liquids, LLC.

APPENDIX D
Survey of scientific studies between May 10, 2016 and September 21, 2016

[Chronologically sequenced]

Teasdale, *et al*., *Cigarette smoke but not electronic cigarette aerosol activates a stress response in human coronary artery endothelial cells in culture*, Drug and Alcohol Dependence, Vol. 163, pp. 256-60 (June 1, 2016).

Farsalinos, *et al*., *Electronic cigarette use in the European Union: analysis of a representative sample of 27,460 Europeans from 28 countries*, Addiction, 111: 2032– 2040 (June 24, 2016).

D'Ruiz, *et al*., *Reductions in biomarkers of exposure, impacts on smoking urge and assessment of product use and tolerability in adult smokers following partial or complete substitution of cigarettes with electronic cigarettes*, BMC Public Health, 2016;16:543 (July 11, 2016).

Olmedo, *et al*., *A direct method for e-cigarette aerosol sample collection*, 149 Environmental Research, pp. 151-56 (August 2016).

APPENDIX E
Survey of scientific studies between September 21, 2016 and April 3, 2019

[Chronologically sequenced]

Thorne, *et al.*, *The mutagenic assessment of an electronic-cigarette and reference cigarette smoke using the Ames assay in strains TA98 and TA100*, Mutation Research/Genetic Toxicology and Environmental Mutagenesis, Vol. 812, pp. 29-38, (December 2016)

Farsalinos, *et al.*, *Emerging Issues in Analytical Chemistry* series, *Analytical Assessment of E-Cigarettes: From Contents to Chemical and Particle Exposure Profiles,* Elsevier Inc (2017).

Hess, *et al.*, E-cigarettes as a source of toxic and potentially carcinogenic metals. 152 Envir. Res. 221 (January 2017).

O'Leary *et al.*, Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices. Victoria, BC: Centre for Addictions Research of BC. (January 2017)

Hyoshin Kim, *et al.*, E-Cigarettes Use Behavior and Experience of Adults: Qualitative Research Findings to Inform E-Cigarette Use Measure Development, *Nicotine & Tobacco Research*, Volume 19, Issue 2, pg. 190-96 (February 1, 2017).

Hajek, *et al., Nicotine delivery to users from cigarettes and from different types of e-cigarettes*. *Psychopharmacology* 234, 773–779 (March 2017).

Morean, *et al.,Vaping to lose weight: Predictors of adult e-cigarette use for weight loss or control*, 66 Addictive Behaviors, 55-59 (March 2017).

Wagener, *Have combustible cigarettes met their match? The nicotine delivery profiles and harmful constituent exposures of second-generation and third-generation electronic cigarette users*, Tob. Control. 2017 Mar; 26(E1): e23–e28.

Caraballo, *et al*., *Quit Methods Used by US Adult Cigarette Smokers, 2014–2016*. Prev. Chronic Dis. 2017;14:160600 (April 13, 2017).

Manzoli, *et al., Cohort study of electronic cigarette use: effectiveness and safety at 24 months,* Tobacco Control, Vol. 26, 3): 284-292 (May 2017).

Zwack, *et al*., *Evaluation of Chemical Exposures at a Vape Shop*, U.S. Dept. of Health and Human Serv. and Centers for Disease Control and Prevention, Health Hazard Evaluation Report 2015-0107-3279 (July 2017).

Farsalinos, *et al*., *E-cigarettes emit very high formaldehyde levels only in conditions that are aversive to users: A replication study under verified realistic use conditions*. 109 Food and Chemical Toxicology, Pt. 1, 90 (November 2017).

Phillips, *et al., Toxicity of the main electronic cigarette components, propylene glycol, glycerin, and nicotine, in Sprague-Dawley rats in a 90-day OECD inhalation study complemented by molecular endpoints*. 109 Food and Chemical Toxicology, Pt. 1, 315 (November 2017).

DeVito, *et al., E-cigarettes: Impact of E-Liquid Components and Device Characteristics on Nicotine Exposure*. Current Neuropharmacology. 2018 ;16(4):438-459 (December 2017).

Abrams, *et al., Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives*, Annu. Rev. Public Health 2018. 39:193–213 (January 2018).

Public Health England, *Independent Expert E-Cigarettes Evidence Review* (Feb. 6, 2018), *available at* https://tinyurl.com/yb9aebkc.

Zwack, *et al*., *Evaluation of Chemical Exposures at Two Vape Shops in Texas*, U.S. Dept. of Health and Human Serv. and Centers for Disease Control and Prevention, Health Hazard Evaluation Report 2016-0120-3307 (May 2018).

O'Connell, *et al., Chemical Composition of myblu™ Pod-System E-Cigarette Aerosols: A Quantitative Comparison with Conventional Cigarette Smoke*, 1st Scientific Summit Tobacco Harm Reduction Kallithea, Greece (June 2018).

Russell, *et al., Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA*, Harm Reduct. J. 15, 33 (June 2018).

Tucker, *et al., Predicting Short-Term Uptake of Electronic Cigarettes: Effects of Nicotine, Subjective Effects, and Simulated Demand*, *Nicotine & Tobacco Research*, Volume 20, Issue 10, Pages 1265–1271 (October 2018).

Goniewicz, *et al*., Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes. *JAMA Netw. Open*. 2018;1(8):e185937 (December 7, 2018).

Buckell, *et al., Should flavours be banned in cigarettes and e-cigarettes? Evidence on adult smokers and recent quitters from a discrete choice experiment*, Tob. Control 2019; 28:168–175 (2019).