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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

NJOY, LLC,

Plaintiff,

v.

iMiracle (HK) Limited; Shenzhen iMiracle Technology Co., Ltd.; Shenzhen Weiboli Technology Co. Ltd.; Vapeonly Technology Co. Ltd.; Guangdong Qisitech Co., Ltd.; Shenzhen Han Technology Co., Ltd.; Magellan Technology Inc.; Shenzhen IVPS Technology Co., Ltd.; Shenzhen Noriyang Technology Co., Ltd.; Shenzhen Innokin Technology Co. Ltd.; Shenzhen Funyin Electronic Co., Ltd.; Shenzhen Pingray Technology; Pastel Cartel LLC; Affiliated Imports, LLC; American Vape Company, LLC a/k/a American Vapor Company, LLC; Dongguan (Shenzhen) Shikai Technology Co., Ltd.; Breeze Smoke, LLC; King Distribution LLC d/b/a

Case No. 2:23-cv-08798

COMPLAINT

1. **UNFAIR COMPETITION (Bus. & Prof. Code § 17200 *et seq.*)**
2. **FALSE ADVERTISING (Bus. & Prof. Code § 17500 *et seq.*)**
3. **FALSE ADVERTISING IN VIOLATION OF THE LANHAM ACT (15 U.S.C. § 1125(a))**
4. **VIOLATION OF THE PREVENT ALL CIGARETTE TRAFFICKING ACT OF 2009 (15 U.S.C. § 375 *et seq.*)**

DEMAND FOR A JURY TRIAL

Lava Vape USA; Buzz Wholesale Inc.; HQD Tech USA, LLC; Maduro Distributors d/b/a The Loon; BFL Metal Production, Ltd.; Dongguan Hengtai Biotechnology Co., Ltd.; Flumgio Technology Ltd.; EVO Brands, LLC; Shenzhen Daosen Vaping Technology Co., Ltd.; Shenzhen Fumot Vaping Technology Co., Ltd.; Flawless Vape Shop Inc.; Flawless Vape Wholesale & Distribution Inc.; Price Point Distributors Inc. d/b/a Prince Point; SV3 LLC d/b/a Mi-One Brands; Thesy, LLC d/b/a Element Vape; VICA Trading Inc. d/b/a Vapesourcing; and PVG2, LLC,

Defendants.

Plaintiff NJOY, LLC ("Plaintiff") brings this complaint against Defendants iMiracle (HK) Limited; Shenzhen iMiracle Technology Co., Ltd.; Shenzhen Weiboli Technology Co. Ltd.; Vapeonly Technology Co. Ltd.; Guangdong Qisitech Co., Ltd.; Shenzhen Han Technology Co., Ltd.; Magellan Technology Inc.; Shenzhen IVPS Technology Co., Ltd.; Shenzhen Noriyang Technology Co., Ltd.; Shenzhen Innokin Technology Co. Ltd.; Shenzhen Funyin Electronic Co., Ltd.; Shenzhen Pingray Technology; Pastel Cartel LLC; Affiliated Imports, LLC; American Vape Company, LLC a/k/a American Vapor Company, LLC; Dongguan (Shenzhen) Shikai Technology Co., Ltd.; Breeze Smoke, LLC; King Distribution LLC d/b/a Lava Vape USA; Buzz Wholesale Inc.; HQD Tech USA, LLC; Maduro Distributors d/b/a The Loon; BFL Metal Production, Ltd.; Dongguan Hengtai Biotechnology Co., Ltd.; Flumgio Technology Ltd.; EVO Brands, LLC; Shenzhen Daosen Vaping Technology Co., Ltd.; Shenzhen Fumot Vaping Technology Co., Ltd.; Flawless

Vape Shop Inc.; Flawless Vape Wholesale & Distribution Inc.; Price Point Distributors Inc. d/b/a Prince Point; SV3 LLC d/b/a Mi-One Brands; Thesy, LLC d/b/a Element Vape; VICA Trading Inc. d/b/a Vapesourcing; and PVG2, LLC (collectively, "Defendants") and alleges as follows:

NATURE OF THE ACTION

1. This action arises out of the Defendants' manufacture, distribution, marketing, and sale of unlawful tobacco products and the impact of those actions on the sale of lawful products manufactured by Plaintiff NJOY. Defendants' actions constitute (i) unlawful, unfair, and fraudulent conduct in violation of the California Unfair Competition Law (Cal. Bus. & Prof. Code § 17200, *et seq.*); (ii) false and misleading advertising in violation of the California False Advertising Law (Cal. Bus. & Prof. Code § 17500, *et seq.*); (iii) false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a); and (iv) violations of the Prevent All Cigarette Trafficking Act of 2009, 15 U.S.C. § 375, *et seq.* Plaintiff NJOY has been and continues to be harmed by the Defendants' conduct and seeks damages, injunctive and other equitable relief, restitution and disgorgement, fees and costs, and such other relief as the Court finds just and proper.

2. Defendants manufacture, distribute, market, and sell flavored disposable vaping devices, referred to herein as "FDVs." FDVs use a battery to heat a nicotine-containing solution, referred to as an "e-liquid," that creates an aerosol that is inhaled by the user. FDVs use e-liquids that are artificially flavored to give the aerosol certain tastes and aromas other than tobacco, such as candy, fruit, and desserts. Unlike pod-based products, which can be refilled and reused, FDVs are disposable and discarded after the e-liquid in the device is depleted.

3. The sale of Defendants' FDVs in California is unlawful. Any sale of FDVs at California retail locations violates the state's ban on flavored tobacco products. Distribution and sale of FDVs is also contrary to federal law and the

policies and actions of the federal Food and Drug Administration ("FDA"). None of the Defendants' FDVs has received premarket authorization from FDA. In many instances, Defendants have not even filed the applications required for premarket approval. Moreover, FDA has repeatedly issued warning letters over the last two years stating that Defendants' FDV products are adulterated and misbranded and making clear that distribution and sale of these products are unlawful. FDA has also issued import alerts authorizing U.S. Customs and Border agents to seize products manufactured and distributed by certain Defendants and has sought civil penalties based on certain products' continued sale. And Defendants have violated shipping, registration, and other requirements imposed by the federal PACT Act.

4. Despite California's flavor ban and the FDA's repeated actions, Defendants continue to manufacture, market, distribute, and sell FDVs. When doing so, Defendants do not tell consumers that their products are unlawful or the subject of FDA actions. To the contrary, Defendants represent, expressly and implicitly, that their FDVs are compliant with regulatory and legal requirements and can lawfully be sold in California and elsewhere. Defendants' representations are false and misleading. Moreover, Defendants' continued manufacture and distribution of unlawful products and avoidance of regulatory requirements are unfair to companies that comply with California's flavor ban and manufacture and sell vapor products that have received premarket approval from FDA.

5. One of those companies is Plaintiff NJOY. Plaintiff manufactures and distributes two brands of e-cigarettes, NJOY Daily and NJOY ACE. Plaintiff distributes for sale in California tobacco-flavored NJOY Daily and its tobacco-flavored NJOY ACE. Plaintiff does distribute or sell any non-tobacco flavored vapor products or FDVs in California. Plaintiff manufactures and distributes menthol-flavored NJOY Daily and ACE products but only to certain locations outside of California.

6. Plaintiff invested significant time, effort, and resources when designing, developing, and testing tobacco-flavored NJOY Daily and NJOY ACE products, and when preparing and submitting the required applications for premarket approval to FDA. On June 10, 2022, after reviewing these voluminous submissions, FDA granted these applications and authorized the sale of tobacco-flavored NJOY Daily and tobacco-flavored NJOY ACE in the United States. Accordingly, in contrast to the Defendants' FDVs, it is legal to sell tobacco-flavored NJOY products in California.

7. Since 2020, the sales volume and market share for FDVs have increased significantly, and a large share of the e-cigarettes and vapor products sold in California are now unlawful FDVs. During the same period, the sales volume and market share for tobacco-flavored products like NJOY Daily and ACE have declined sharply.

8. Although some underage consumers purchase and use FDVs, Plaintiff's claims are not based on sales to or purchases by underage individuals. Plaintiff does not market, distribute, or sell NJOY products to underage individuals. And Plaintiff has taken and continues to take significant measures to prevent underage access to and underage use of NJOY products and to prevent minors from being exposed to NJOY marketing.

9. Plaintiff's claims instead are based on adult consumers, the adult market for e-cigarettes, and the Defendants' impact on that market. A massive number of adult consumers have purchased and continue to purchase Defendants' unlawful FDV products instead of lawful products like tobacco-flavored NJOY Daily and ACE, causing Plaintiff to suffer lost sales, lost profits, and other economic harm. This harm is the direct result of the Defendants' unlawful, unfair, and fraudulent conduct—without which their products could not be sold—and Plaintiff will continue to suffer harm without relief from this Court.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action pursuant to (i) 15 U.S.C. § 1121, as an action for violation of the Lanham Act, 15 U.S.C. § 1051 *et seq*.; (ii) 15 U.S.C. § 378(a), as an action for violation of the Prevent All Cigarette Trafficking Act of 2009; and (iii) 28 U.S.C. § 1367(a), pursuant to the principles of supplemental jurisdiction.

11. This Court has personal jurisdiction over each Defendant. Defendants have had, and continue to have, significant contacts with California, including by manufacturing and distributing FDVs to be sold in California, shipping FDVs to California, delivering FDVs to California, marketing and advertising FDVs in California, and selling FDVs in California. Each Defendant also has purposefully availed itself of the benefits of California law. In addition, Plaintiff's claims arise out of and relate to each Defendant's contacts with California. And it would not offend notions of fair play and due process to exercise of personal jurisdiction over each Defendant.

12. A substantial part of the events and omissions giving rise to the Plaintiff's causes of action occurred in or emanated from this District. Pursuant to 28 U.S.C. § 1391(a), venue is therefore proper in this District.

THE PARTIES

13. Plaintiff NJOY, LLC is a limited liability company organized under the laws of Delaware with its principal place of business at 9977 N. 90th Street, Scottsdale, Arizona 85258.

14. Defendant iMiracle (HK) Limited ("iMiracle HK") is a Hong Kong limited liability company that has its principal place of business in Hong Kong. Defendant iMiracle (HK) manufactures, markets, distributes, and/or sells FDVs, including Elf Bar, EB, EB Create, and EB Design products, owns or controls

businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

15. Defendant iMiracle HK is an affiliate of Defendant Shenzhen iMiracle Technology Co. Ltd. ("Shenzhen iMiracle"), a Chinese limited company with its principal place of business at RM 306-311, Tianshuzuo, No. 6099 Ba'an Avenue, Bao'an District, Shenzhen, China 518000. Defendant Shenzhen iMiracle manufactures, markets, distributes, and/or sells FDVs, including Elf Bar, EB, EB Create, and EB Design products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

16. Upon information and belief, iMiracle HK and Shenzhen iMiracle are both affiliates of Defendant Shenzhen Weiboli Technology Co. Ltd. ("Shenzhen Weiboli"), which is located at the same address as Shenzen iMiracle. Defendant Shenzhen iMiracle manufactures, markets, distributes, and/or sells FDVs, including Elf Bar, EB, EB Create, and EB Design products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

17. Defendant Vapeonly Technology Co. Ltd. ("Vapeonly") is a Chinese limited company with its principal place of business at Room 306-311, Tianshu Building, No. 6099, Bao'an Avenue, Bao'an District, Shenzhen, China 518000. Defendant Vapeonly manufactures, markets, distributes, and/or sells FDVs, including Elf Bar, EB, EB Create, and EB Design products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

18. Defendant Guangdong Qisitech Co., Ltd. ("Guangdong Qisitech") is a Chinese limited company with an address at Fuxing Road, Changan Twon Room 201, Building 3, No. 36, Dongguan City, Guangdong Province, China 52300.

Defendant Guangdong Qisitech manufactures, markets, distributes, and/or sells FDVs, including Elf Bar, EB, EB Create, and EB Design products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

19. Defendants iMiracle HK, Shenzhen iMiracle, Shenzhen Weiboli, Vapeonly, and Guangdong Qisitech are collectively referenced in this Complaint as "the Elf Bar Defendants."

20. Defendant Shenzhen Han Technology Co., Ltd. ("Shenzhen Han") is a Chinese limited company with an address at Qianwan Hard Technology Park, Baoan District, Shenzhen, Guangdong, China 518126. Defendant Shenzhen Han manufactures, markets, distributes, and/or sells FDVs, including Lost Mary products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

21. Defendant Shenzhen IVPS Technology Co., Ltd. ("Shenzhen IVPS") is a Chinese limited company with an address at 101, Building B8, No. 2, Cengayo, Industrial Area, Yuluv Community, Yutang Subdistrict, Guangming District, Shenzhen, China 518001. Shenzhen IVPS also has an address at Room 101, Building 69, Liantang Indus. Zone Fenghuang Street, Guangming New District, Shenzhen, China 518000. Defendant Shenzhen IVPS manufactures, markets, distributes, and/or sells FDVs, including Hyde products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

22. Defendant Shenzhen Noriyang Technology Co., Ltd. ("Shenzhen Noriyang") is a Chinese limited company with a principal place of business at Room 303, Building A, Zhonghengsheng High-Tech Park, Xinyu Road, Shajing Town, Baoan District, Shenzhen, Guangdong Province, China, 518104. Defendant Noriyang manufactures, markets, distributes, and/or sells FDVs, including Hyde

products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

23. Defendant Magellan Technology Inc. ("Magellan") is a corporation formed under the laws of the State of New York with a principal place of business at 2225 Kenmore Avenue, Buffalo, NY 14207. Defendant Magellan manufactures, markets, distributes, and/or sells FDVs, including Hyde products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

24. Defendants Shenzhen IVPS, Shenzhen Noriyang, and Magellan are collectively referenced in the Complaint as "the Hyde Defendants."

25. Defendant Shenzhen Innokin Technology Co., Ltd. ("Shenzhen Innokin") is a Chinese corporation with a principal place of business at 2nd Floor, Building 6 & Unit B, 3rd Floor, Building 10, Xinxintian Industrial Park, Xinsha Road, Shajing, Bao'an District, Shenzhen, China. Defendant Shenzhen Innokin manufactures, markets, distributes, and/or sells FDVs, including Esco and Esco Bar products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

26. Defendant Shenzhen Funyin Electronic Co., Ltd. ("Funyin Electronic") is a Chinese limited company with its principal place of business at 205 and 401, Building A3, Fuyan Ind. Zone Tangwei Community, Fuhai St., Bao'an Dist. Shenzhen, Guangdong, China 518000. Defendant Funyin Electronic manufactures, markets, distributes, and/or sells FDVs, including Esco and Esco Bar products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

27. Defendant Shenzhen Pingray Technology ("Pingray") is a Chinese limited company with its principal place of business at 3rd Floor, No. 9 Building, HuaFeng International Made City, WanLe Rd., Shajing St., Bao'an District,

Shenzhen City, China 518000. Defendant Pingray manufactures, markets, distributes, and/or sells FDVs, including Esco and Esco Bar products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

28. Defendant American Vape Company, LLC a/k/a American Vapor Company, LLC ("AVC") is a Texas limited liability company located at 13326 Immanuel Road, Pflugerville, Texas 78660. AVC markets, distributes, and sells FDVs, including Esco and Esco Bar products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control. AVC also co-owns the trademark for FDVs sold under the trade name "Esco Bar" and the trademark to the trade name "Pastel Cartel." AVC operates the website www.americanvaporcompany.com.

29. Defendant Pastel Cartel LLC ("Pastel Cartel") is a limited liability company organized under the laws of Texas with a principal place of business at 11305 Four Points, Austin, TX 78726. Pastel Cartel markets, distributes, and sells FDVs, including Esco Bar-branded products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control. Pastel Cartel operates the e-commerce website www.escobars.com.

30. Defendant Affiliated Imports, LLC ("Affiliated Imports") is a Texas limited liability company located at 13326 Immanuel Road, Pflugerville, Texas 78600. Affiliated Imports is registered to AVC and acts as AVC's and Pastel Cartel's consignee and importer for shipments of Esco Bar FDVs entering the United States and/or previously engaged in such conduct.

31. Defendant Dongguan (Shenzhen) Shikai Technology Co., Ltd. ("Shikai Technology" is a Chinese limited company with its principal place of business at L5 Block A Shuangjinhui Tongfuyu Fuyong, Baoan Shenzhen, Guangdong, China

518101, and a manufacturing address of No. 6, Shayong Road, Shajiao Community, Humen Town, Dongguan City, Guangdong Province, China,(Mainland). Defendant Shikai Technology manufactures, markets, distributes, and/or sells FDVs, including Breeze products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

32. Defendant Breeze Smoke, LLC ("Breeze Smoke") is a limited liability company formed under the laws of Michigan with a principal place of business at 4654 Lilly Ct., West Bloomfield, MI 48323, and a distribution address of 26056 Van Dyke Ave., STF 3537, Centerline, MI 48015. Defendant Breeze Smoke manufactures, markets, distributes, and/or sells FDVs, including Breeze products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

33. Defendant King Distribution LLC d/b/a Lava Vape USA ("King Distribution") is a corporation formed under the laws of New Jersey with a principal place of business at 356 Getty Avenue, Clifton, NJ 07011. Defendant King Distribution manufactures, markets, distributes, and/or sells FDVs, including Lava products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

34. Defendant Buzz Wholesale Inc. ("Buzz Wholesale") is a corporation formed under the laws of New Jersey with a principal place of business at 356 Getty Ave #6, Clifton NJ 07011. Defendant Buzz Wholesale operates the e-commerce website www.lavapods.com. Defendant Buzz Wholesale markets, distributes, and sells FDVs manufactured by King Distribution, including Lava products, and/or previously engaged in such conduct.

35. Defendant HQD Tech USA, LLC ("HQD") is a limited liability company organized under the laws of Florida, with a principal place of business at 1129 W. 68th St., Hialeah, FL 33014. Defendant HQD manufactures, markets,

distributes, and/or sells FDVs, including HQD products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control. HQD operates the e-commerce website, www.hqdtechusa.com, and/or did so in the past.

36. Defendant Loon Tobacco LLC ("The Loon") is a Minnesota limited liability company registered to do business at 227 Twillite Terrace, Circle Pines, MN 55014. Defendant The Loon manufactures, markets, distributes, and/or sells FDVs, including Loon Maxx, Loon Air+, Pluto Bars, Juicebox, King Pluto Enzo, and King Pluto Due products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

37. Defendant BFL Metal Production, Ltd. ("BFL Metal Production") is a Chinese company with its principal place of business at No. 15A Shop, 2nd Floor, Building 6 No. 10 Laixiang Road, Chancheng, Foshan, China 528000. Defendant BFL Metal Production manufactures, markets, distributes, and/or sells FDVs, including Fume and LD products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

38. Defendant Dongguan Hengtai Biotechnology Co., Ltd. ("Dongguan Hengtai") is a Chinese company with its principal place of business at Room 5028, No. 915, Chang'an Section Tai'an Road, Chang'an Town Dongguan, Guangdong, China 518000. Defendant Dongguan Hengtai manufactures, markets, distributes, and/or sells FDVs, including Mr. Fog products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

39. Defendant Flumgio Technology Ltd. ("Flumgio") is a Hong Kong corporation with its principal place of business at Rm 21, Unit A, 1F, Tn Wui Industrial Bldg., No. 3 Hing Wong Street, Tuen Mun, M.T. Hong Kong. Defendant

Flumgio manufactures, markets, distributes, and/or sells FDVs, including Flum products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

40. Defendant Shenzhen PD Technology Co. Ltd. ("Shenzhen PD") is a Chinese corporation that is affiliated with Defendant Flumgio. Upon information and belief, Defendant Shenzhen PD's principal place of business at the same location as Flumgio. Defendant Shenzhen PD manufactures, markets, distributes, and/or sells FDVs, including Flum products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control.

41. Defendant Shenzhen Daosen Vaping Technology Co., Ltd. ("Shenzhen Daosen") is a Chinese limited company with an address at #501, Building B1, Quanzhi Zhihui Park, Ligang S. Road, Shajin Street, Baon'an District, Shenzhen, China 518104. Defendant Shenzhen Daosen manufactures, markets, distributes, and/or sells FDVs, including Puff Bar products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control. Defendant Shenzhen Daosen markets and sells FDVs from the website www.dsvaping.en.made-in-china.com and/or has done so in the past.

42. Defendant EVO Brands, LLC ("EVO Brands") is a Delaware limited liability company with a registered address at 251 Little Falls Drive, Wilmington, Delaware 19808. Defendant EVO Brands owns all of the foreign and domestic Puff Bar-related trademarks. On July 6, 2022, EVO Brands submitted a change-of-address form to the U.S. Patent and Trademark Office, proposing to change its address to 1700 Santa Fe Avenue, Ste. 420, Los Angeles, California.

43. Defendant PVG2, LLC ("PVG2") is a Delaware limited liability company with a registered address at 251 Little Falls Drive, Wilmington, Delaware 19808. PVG2 is affiliated with EVO Brands. PVG2 has 11 branches across 11

states, three of which are registered to the same address as EVO Brands. PVG2 markets, distributes, and sells FDVs from the website www.puffbar.com, including Puff Bar products, and/or has done so in the past.

44. Defendant Shenzhen Fumot Vaping Technology Co., Ltd. ("Shenzhen Fumot") is a Chinese limited company with an address of A2907, Building A Longguan Jiuzuan Business Center, Minzhi Longhua, Shenzhen, China 518000. Defendant Shenzhen Fumot manufactures, markets, distributes, and/or sells FDVs, including RandM products, owns or controls businesses engaged in such conduct, and/or previously engaged in such conduct or possessed such ownership or control. Shenzhen Fumot sells FDVs from its website www.randm-shop.online and through third-party wholesale websites such as www.made-in-china.com, including RandM products, and/or has done so in the past.

45. Defendant Flawless Vape Shop Inc. is a California corporation with a registered address at 1021 E. Orangethorpe Avenue, Anaheim, California 92801. On various filings with the California Secretary of State, Defendant Flawless Vape Shop Inc. lists its principal office at 17421 Nichols Lane, Ste. P, Huntington Beach, California 82647. Defendant Flawless Vape Shop Inc. markets, distributes, and sells FDVs to consumers in California and across the country, including from the website www.flawlessvapeshop.com, and/or has done so in the past.

46. Defendant Flawless Vape Wholesale & Distribution Inc. is a California corporation with a registered address at 1021 E. Orangethorpe Avenue, Anaheim, California 92801. On various filings with the California Secretary of State, Defendant Flawless Vape Wholesale & Distribution Inc. lists its principal office at 5589 E. Santa Ana Canyon Road, Anaheim, California 92807. Defendant Flawless Vape markets, distributes, and sells FDVs to consumers in California and across the country, including from the website www.flawlessvapeshop.com, and/or has done so in the past.

47. Defendant Price Point Distributors Inc. d/b/a Prince Point ("Price Point") is a New York corporation with its principal place of business at 500 Smith Street, Farmingdale, New York 11735. Defendant Price Point's fulfillment warehouse is located at that same address. Defendant Price Point markets, distributes, and sells FDVs to consumers in California and across the country, including from the website www.pricepointny.com, and/or has done so in the past.

48. Defendant SV3 LLC d/b/a Mi-One Brands ("Mi-One") is an Arizona limited liability company with its corporate headquarters at 4908 E. McDowell Road, Phoenix, Arizona 85008. Mi-One's fulfillment warehouse is located at that same address. Defendant Mi-One also has a fulfillment warehouse at 3325 W. Alibaba Lane, #616, Las Vegas, NV 89118. Defendant Mi-One markets, distributes, and sells FDVs to consumers in California and across the country, including from the website https://www.mipod.com, and/or has engaged in such conduct in the past.

49. Defendant Thesy, LLC d/b/a Element Vape ("Element Vape") is a California limited liability company with a principal place of business at 10620 Hickson Street, El Monte, California 91731. Defendant Element Vape's fulfillment warehouse is located at that same address. Defendant Element Vape markets, distributes, and sells FDVs to consumers in California and across the country, including from the website www.elementvape.com, and/or has engaged in such conduct in the past.

50. Defendant VICA Trading Inc. d/b/a Vapesourcing ("Vape Sourcing") is a California corporation with a principal place of business at 3045 Edinger Avenue, Tustin, California 92780. Defendant Vape Sourcing's fulfillment warehouse is located at that same address. Defendant Vape Sourcing markets, distributes, and sells FDVs to consumers in California and across the country, including from the website www.vapesourcing.com, and/or has engaged in such conduct in the past.

FACTUAL ALLEGATIONS

I. Premarket Authorization Requirements under Federal Law

51. In 2016, pursuant to the Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. § 387 *et seq.* ("Tobacco Control Act"), FDA adopted the "Deeming Rule." 21 C.F.R. § 1143.1. The Deeming Rule provided that e-cigarettes and electronic nicotine delivery devices, including FDVs, would be treated as "tobacco products" under the Tobacco Control Act and thus would be subject to the Tobacco Control Act and regulated by FDA.

52. The Tobacco Control Act and FDA's regulatory regime generally require that companies obtain marketing authorization from FDA before any "new" tobacco product—a tobacco product that was not on the market in the United States as of February 15, 2007—can be sold in the United States.

53. Before introducing a new tobacco product to the United States market, a company must submit a marketing application to FDA to receive authorization. FDA provides three possible pathways to market for new tobacco products: premarket tobacco product applications ("PMTA"), substantial equivalence reports, and requests for exemption from demonstrating substantial equivalence.[1]

54. The substantial equivalence and request for exemption from substantial equivalence pathways compare the new tobacco product to a pre-existing predicate product that was available in the United States as of February 15, 2007. No valid pre-existing e-cigarette or vapor product has been identified. Accordingly, applications accepted through these two pathways have been limited to cigarettes, cigars, hookah tobacco, roll-your-own tobacco, smokeless tobacco products, and

[1] Market and Distribute a Tobacco Product, U.S. Food & Drug Administration (Apr. 11, 2022) (available at https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product).

rolling papers, and the only premarket applications for e-cigarette and vapor products accepted by FDA have been through the PMTA pathway.[2]

55. To obtain market approval, a PMTA must demonstrate to FDA that marketing the new tobacco product is "appropriate for the protection of the public health." 21 U.S.C. § 387g; 21 C.F.R. § 1114.7(c). This determination turns in part on the increased or decreased likelihood that existing users of tobacco products will stop using those products, as well as the increased or decreased likelihood that those who do not use tobacco products will start.

56. In practice, FDA's PMTA process requires that an applicant submit a vast array of scientific data and analysis, at significant time and expense to the applicant. The applicant must provide detailed scientific information about consumer behavioral factors and anticipated product usage patterns. It also must provide extensive clinical and nonclinical data regarding the toxicological content of the product and its effects on users and nonusers, including in vitro and in vivo toxicological studies, and an analysis of all relevant scientific literature and other relevant scientific analyses.[3] PMTAs therefore can take years to develop and comprise many thousands of pages of data.

57. When FDA issued the final Deeming Rule, and made e-cigarettes and vapor products subject to the Tobacco Control Act, the agency also announced a compliance policy for premarket review of those products. Under this policy, e-cigarettes and vapor products that were on the market in the United States as of August 8, 2016, could remain on the market provided the manufacturer submitted a

[2] *Id.*

[3] *See generally* FDA, Guidance for Industry, Premarket Tobacco Product Applications for electronic Nicotine Delivery Systems (Revised) (March 2023) (available at https://www.fda.gov/media/127853/download).

PMTA for the product within 24 months of the rule's effective date, August 8, 2018.[4] That deadline was later extended to September 9, 2020.[5] In contrast to products available as of August 8, 2016, under the Deeming Rule and the FDA's compliance policy, any e-cigarette or vapor product that was not on the market on August 8, 2016 could no longer be sold in the United States.

58. In April 2020, FDA published a report setting forth the agency's revised enforcement priorities for e-cigarettes and vapor products.[6] In this document, FDA "describes how [it] intend[s] to prioritize [its] enforcement resources with regard to the marketing of certain deemed tobacco products that do not have premarket authorization."[7]

59. The FDA's enforcement policy states that FDA "intends to prioritize enforcement against" the following kinds of products: (1) "[a]ny flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product)," (2) "[a]ll other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access," and (3) "[a]ny ENDS product that is targeted to minors or whose marketing is likely to promote use of

[4] Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28974, 28977-78 (May 10, 2016).

[5] *See* FDA Statement, Coronavirus (COVID-19) Update: Court Grants FDA's Request for Extension of Premarket Review Submission Deadline for Certain Tobacco Products Because of Impacts from COVID-19 (April 23, 2020) (available at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-court-grants-fdas-request-extension-premarket-review-submission-deadline).

[6] Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised) at 2, Guidance for Industry, FDA (April 2020) (available at https://www.fda.gov/media/133880/download).

[7] *Id.*

ENDS by minors."[8] FDA also said that it "intends to prioritize enforcement of any ENDS product that is offered for sale after September 9, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application)."[9]

60. The Tobacco Control Act and the FDA's regulatory process and requirements apply to both products that contain nicotine derived from tobacco and products that contain synthetic nicotine that did not come from tobacco plants (referred to as non-tobacco nicotine or "NTN").[10] Indeed, in response to the increased availability and sale of NTN, Congress passed a law in March 2022 that made clear that the FDA's authority to regulate tobacco products extends to products containing nicotine from any source, including NTN.[11] Congress further provided that synthetic nicotine products could remain on the market for only 90 days, and FDA has never issued a compliance policy that modified that provision.[12]

61. FDA issued its first marketing denial orders concerning e-cigarette and vapor products on August 26, 2021, when it denied premarket approval applications for approximately 55,000 flavored e-cigarette and vapor products.[13]

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[8] *Id.* at 3.

[9] *Id.*

[10] Regulation & Enforcement of Non-Tobacco Nicotine (NTN) Products, U.S. Food & Drug Administration (June 9, 2023) (available at https://www.fda.gov/tobacco-products/products-ingredients-components/regulation-and-enforcement-non-tobacco-nicotine-ntn-products).

[11] *Id.*

[12] *Id.*; *see also* Pub. L. 117-35, Sec. 111(d) (March 15, 2022).

[13] *See* E-cigarette Unit Sales by Product and Flavor Type, and Top-Selling Brands, United States, 2020-2022, Morbidity & Mortality Weekly Rpt. (Centers for Disease Control and Prevention) (Jun. 23, 2023).

62. As of September 2023, FDA had authorized the sale of 45 new tobacco products through the PMTA pathway, including 23 tobacco-flavored e-cigarette and vapor products.[14]

63. FDA has not authorized the marketing or sale of any FDV.

II. California's State-Wide Flavor Ban and Restrictions on Tobacco Products

64. California has adopted an extensive regulatory framework for tobacco products that seeks to ensure that only legal products are sold to consumers and to prevent youth access to these products. For example, under California's Stop Tobacco Access to Kids Enforcement Act ("STAKE Act"), the sale of e-cigarettes, including FDVs, to persons under the age of 21 is prohibited both at physical retail locations and by delivery sales. Cal. Bus. & Prof. Code §§ 22958, 22975. Moreover, retailers, wholesalers, and distributors of tobacco products must obtain licenses. *Id.* §§ 22972, 22975.

65. California also requires that delivery sellers of e-cigarettes and vapor products verify the consumer's age by checking the consumer's information against "an appropriate database of government records." *Id.* § 22963(b). The seller also must verify that the billing address on the check or credit card offered for payment matches the address listed in the database. *Id*. § 22975(b). In addition, the distributor or seller must make a telephone call after 5 p.m. to the purchaser confirming the order before it can ship the tobacco products. *Id*. § 22975(b)(3).

66. Tobacco products also must be delivered in a container that is conspicuously labeled with the words, "CONTAINS TOBACCO PRODUCTS: SIGNATURE OF PERSON 21 YEARS OF AGE OR OLDER REQUIRED FOR

[14] Premarket Tobacco Product Marketing Granted Orders, U.S. Food & Drug Administration (Sept. 20, 2023) (available at https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders).

DELIVERY." And a person aged 21 or older must provide a signature to receive a tobacco product delivery. *Id*. § 22963.

67. California also imposes a tax on e-cigarettes and vapor products, including FDVs, at the rate of 61.74% of the wholesale price. E-cigarettes and vapor products, including FDVs, are also subject to a 12.5% sales tax. And all sellers of these products, including those that are located outside the state but sell to consumers in the state, are required to collect the tax and remit it to the California Department of Tax and Fee Administration. Cal. Rev. & Tax. Code §§ 31002, 30130.51.

68. In 2020, California enacted Senate Bill 793, which banned the sale of flavored tobacco products in the state. After withstanding a voter referendum in November 2022, the bill amended the California Health and Safety Code by adding a provision that prohibits selling, offering for sale, or possessing with the intent to sell or offer to sell "a flavored tobacco product or a tobacco product flavor enhancer." Cal. Health & Safety Code § 104559.5(b)(1). A "flavored tobacco product is one "that contains a constituent that imparts a characterizing flavor." *Id*. § 104559.5(a)(4). A "characterizing flavor" is "a distinguishable taste or aroma, or both, *other than the taste or aroma of tobacco*, imparted by a tobacco product or any byproduct produced by the tobacco product." *Id*. § 104559.5(a)(1) (emphasis added). The law broadly defines "tobacco product" to include any "product containing, made, or derived from tobacco or nicotine." *Id*. § 104495(b).

69. California's ban on flavored tobacco products applies to all FDVs and makes the sale of FDVs at retail locations in California illegal under state law.

III. NJOY Products and the FDA's Market Approval Orders

70. The NJOY brand was founded in 2006 with the formation of NJOY Inc. and was a pioneer in vaping and one of the first major electronic cigarettes brands in the United States. In 2017, NJOY LLC purchased the assets of NJOY Inc., including the NJOY brand.

71. Plaintiff is the only company that has partnered with the National Institute of Drug Abuse ("NIDA") to develop, test, and manufacture a Standard Research Electronic Cigarette ("SREC"), which plays a critical role in clinical and public health research in the United States. SRECs are used as a consistent, well-characterized investigational product in independent clinical studies funded by NIDA and the National Institutes of Health. SRECs are currently being used in eleven ongoing clinical studies and planned for use in at least five additional studies to expand scientific knowledge regarding the impact of e-cigarettes and vapor products on public health.

72. Plaintiff's mission is to offer a range of electronic nicotine products for adult consumers in the United States looking for a potentially less harmful alternative to traditional combustible cigarettes. Plaintiff currently offers two commercial product lines, NJOY Daily and NJOY ACE. NJOY Daily is a disposable electronic cigarette that has the same form factor as a traditional cigarette. NJOY ACE is a pod vaporizer device that comprises a reusable and rechargeable electronic device and a disposable pod that stores a vaporizable liquid and is inserted into the electronic device for use. Once the liquid in an ACE pod is depleted, the adult consumer can replace the used ACE pod with a new one.

73. Plaintiff has made and continues to make substantial investments into research and development, including designing, engineering, manufacturing, and seeking regulatory authorization for its products. In addition, Plaintiff has invested and continues to invest significant resources into marketing NJOY ACE and NJOY Daily products.

74. The PMTAs for tobacco-flavored and menthol-flavored NJOY ACE and NJOY Daily products were received by FDA on March 10, 2020. The applications totaled tens of thousands of pages, including numerous scientific studies and extensive consumer research. Plaintiff submitted scientific evidence

demonstrating NJOY ACE and NJOY Daily products are less harmful than combustible cigarettes and showing meaningful switching among consumers from combustible cigarettes to NJOY products. Plaintiff also submitted youth prevalence data showing miniscule levels of youth interest in NJOY products.

75. In early 2020, Plaintiff voluntarily removed blueberry- and watermelon-flavored products from the market.

76. After two years of rigorous scientific review, FDA issued an order on April 26, 2022, granting market authorization to the NJOY ACE device and three tobacco-flavored NJOY ACE pods, Classic Tobacco 2.4%, Classic Tobacco 5%, and Rich Tobacco 5%.[15] On June 10, 2022, FDA granted premarket authorization to two tobacco-flavored NJOY Daily products, NJOY Daily Rich Tobacco 4.5% and NJOY Daily Extra Rich Tobacco 6%.[16]

77. When authorizing Plaintiff's NJOY products, FDA made the following findings regarding the positive impacts on the public health that these products provide as compared to traditional combustible cigarettes:

- "[T]hese products have the potential to benefit adult smokers who switch completely or significantly reduce their cigarette consumption."[17]
- "The NJOY User Study demonstrated that switching from combusted cigarettes to the new ENDS products does occur among current adult

[15] FDA Issues Marketing Decisions on NJOY Ace E-Cigarette Products, U.S. Food & Drug Admin. (April 26, 2022) (available at https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-decisions-njoy-ace-e-cigarette-products).

[16] FDA Issues Marketing Decisions on NJOY Daily E-Cigarette Products, U.S. Food & Drug Admin. (June 10, 2022) (available at https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-decisions-njoy-daily-e-cigarette-products).

[17] FDA, Technical Project Lead (TPL) Review of PMTAs, NJOY LLC, at 6 (April 25, 2022) (available at https://www.fda.gov/media/164458/download?attachment).

smokers. The applicant has therefore demonstrated the potential for these products to benefit adult smokers as compared to continued exclusive cigarette use."[18]

- "Chemical testing submitted in the PMTAs was sufficient to determine that overall harmful and potentially harmful constituent (HPHC) levels in the aerosol of these products are lower than in combusted cigarette smoke. The overall toxicological risk to the users of the new products is lower compared to cigarettes due to significant reductions in aerosol HPHCs of the new products compared to cigarettes."[19]

78. Based on these and other findings, FDA concluded that "permitting marketing of the new products . . . is appropriate for the protection of the public health."[20]

79. NJOY ACE is the only FDA-authorized pod vaporizer device on the market in the United States.

80. Plaintiff's authorized products are subject to continued FDA oversight. This includes post-market surveillance and reporting requirements that cover NJOY's: labeling; advertising, marketing and promotional materials; changes to manufacturing, facilities and controls; stability monitoring and testing; ongoing and completed studies; scientific investigations and literature; adverse experiences and changes to overall risk and health risks; sales and distribution data; policies and procedures regarding age- and identity-verification; policies and procedures regarding restrictions on access for individuals under the minimum age of sale; consumer evaluation and research studies; creation and dissemination of labeling,

[18] *Id.* at 6.

[19] *Id.*

[20] FDA, Marketing Granted Orders for NJOY ACE Products at 1 (April 26, 2022) (available at https://www.fda.gov/media/164457/download?attachment).

advertising, marketing and/or promotional materials; advertising and marketing plans; media tracking and optimization; and actual delivery of advertising impressions.

81. In addition to tobacco-flavored NJOY ACE and NJOY Daily products, Plaintiff currently distributes for sale menthol-flavored NJOY ACE and NJOY Daily products to certain locations outside of California. Plaintiff submitted PMTAs for these menthol-flavored products on March 10, 2020, and amended PMTAs on December 2, 2022. FDA has not taken action on those applications, and they remain pending. Consistent with the FDA's current enforcement policy discussed above, the agency has not taken action against Plaintiff or any retailer or distributor for distributing or selling these menthol-flavored NJOY products.

IV. Defendants' FDVs and FDA Actions Concerning Those Products

82. Since 2020, the number of brands of FDVs sold in the United States has increased significantly.[21] Many of these products are manufactured in and imported from China.[22] One observer described the current market for vapor products as

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[21] *See, e.g.*, Matthew Perrone, Thousands of unauthorized vapes are pouring into the US despite the FDA crackdown on fruity flavors, Associated Press (June 26, 2023) (available at https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f) ("The number of different electronic cigarette devices sold in the U.S. has nearly tripled to over 9,000 since 2020, driven almost entirely by a wave of unauthorized disposable vapes from China, according to tightly controlled sales data obtained by the Associated Press."); Lauren Clason, Disposable vape sales soared after FDA focused efforts elsewhere, Roll Call (Jun. 22, 2023) (available at https://rollcall.com/2023/06/22/disposable-vape-sales-soared-after-fda-focused-efforts-elsewhere/) ("The total number of e-cigarette brands . . . increased from 184 to 269, or 46.2 percent" between January 2020 and December 2022).

[22] *See, e.g.*, Yuki Noguchi, They're illegal. So why is it so easy to buy the disposable vape favored by teens? NPR (July 14, 2023) (available at https://www.npr.org/sections/health-shots/2023/07/14/1186291971/theyre-illegal-so-why-is-it-so-easy-to-buy-the-disposable-vapes-favored-by-teens) ("Nearly all the world's e-cigarettes — 90% — come from factories in Shenzhen, China").

follows: "hundreds of new varieties appear each month. Companies copy each other's designs, blurring the line between the real and counterfeit. Entrepreneurs can launch a new product by simply sending their logo and flavor requests to Chinese manufacturers, who promise to deliver tens of thousands of devices within weeks."[23]

83. Foreign manufacturers direct their products into the United States in ways that limit, if not avoid, any review, inspection, oversight, or regulatory process before the products are sold to U.S. consumers.[24]

84. FDA has not granted premarket approval to any non-tobacco- or non-menthol-flavored disposable product. Instead, the agency has repeatedly issued warning letters making clear that it is unlawful to market distribute and sell FDVs, including the specific products manufactured, marketed, distributed, and sold by these Defendants.

85. As of September 30, 2023, for example, FDA had issued and posted over 200 warning letters stating that Elf Bar products—which have been rebranded as EB, EB Create, and EB Design products—cannot be sold without a marketing authorization order and had been misbranded.[25]

[23] Matthew Perrone, Thousands of unauthorized vapes are pouring into the US despite the FDA crackdown on fruity flavors, Associated Press (June 26, 2023) (available at https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f).

[24] *Id.*

[25] *See* FDA, Warning Letters, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

86. In addition, FDA has issued at least two warning letters stating that Lost Mary products cannot be sold without a marketing authorization order and had been misbranded.[26]

87. FDA has issued at least two warning letters stating that Hyde products cannot be sold without a marketing authorization order and had been misbranded.[27]

88. FDA has issued at least sixteen warning letters explaining that Esco Bar products cannot be sold without a marketing authorization order and had been misbranded, including one letter directed to Defendants Shenzhen Innokin and Pastel Cartel.[28]

89. FDA has issued at least two warning letters stating that Breeze Smoke products cannot be sold without a marketing authorization order and had been misbranded, including one warning letter sent directly to Defendant Breeze Smoke.[29]

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[26] *See* FDA, Warning Letters, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

[27] *See* FDA, Warning Letters, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

[28] Warning Letter to Shenzhen Innokin (May 23, 2023), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/shenzhen-innokin-technology-co-ltd-657347-05252023; *see also* FDA, Warning Letters, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

[29] Warning Letter to Breeze Smoke (May 23, 2023) (available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/breeze-smoke-llc-655821-05252023); *see also* FDA, Warning Letters, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

90. FDA has issued at least seven warning letters stating that Lava products cannot be sold without a marketing authorization order and had been misbranded, including one warning letter sent directly to Defendant King Distribution.[30]

91. FDA has issued at least three warning letters explaining that Loon products cannot be sold without a marketing authorization order and had been misbranded, including one letter sent directly to Defendant The Loon's website.[31]

92. FDA has issued at least six warning letters stating that Puff Bar products cannot be sold without a marketing authorization order and had been misbranded, including one letter sent directly to Defendants EVO Brands and PGV2.[32]

93. On August 8, 2022, FDA issued a warning letter to Mr. Fog's website stating that Mr. Fog products cannot be sold without a marketing authorization order and had been misbranded.[33]

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[30] Warning Letter to King Distribution (September 14, 2023) (available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/king-distribution-llc-dba-lava-vape-usa-667203-09142023); *see also* FDA, Warning Letters, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

[31] *See* Warning Letter to Maduro Distributors d/b/a The Loon (Aug. 20, 2021) (available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/maduro-distributors-dba-loon-617040-08202021); *see also* FDA, Warning Letters, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

[32] *See* Warning Letter to EVO Brands, LLC and PVG2, LLC (Oct. 6, 2022) (available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/evo-brands-llc-and-pvg2-llc-dba-puff-bar-643091-10062022; *see also* FDA, Warning Letters, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

[33] *See* Warning Letter to Dongguan Hengtai Biotechnology, Co. Ltd d/b/a/ Mr. Fog (Aug. 8, 2022) (available at https://www.fda.gov/inspections-compliance-

94. On November 26, 2022, FDA sent a warning letter to Defendant Shenzhen Fumot stating that Fumot and RandM products cannot be sold without a marketing authorization order and had been misbranded.[34]

95. On July 20, 2023, FDA sent a warning letter to Defendant HQD stating that HQD products cannot be sold without a marketing authorization order and had been misbranded.[35]

96. Moreover, FDA has taken additional actions with respect to some of the Defendants' products. On May 17, 2023, FDA issued an import alert specifying that Elf Bar, Esco Bar, and certain other brands of FDVs should be refused admission into the United States and detained without inspection because the products are unlawful.[36] FDA subsequently reiterated and updated this import alert on September 17, 2023.[37]

97. On September 28, 2023, FDA announced that it had issued complaints for civil penalties against 22 retailers based on the sale of Elf Bar and EB products.[38]

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enforcement-and-criminal-investigations/warning-letters/dongguan-hengtai-biotechnology-co-ltd-dba-mr-fog-638700-08012022).

[34] Warning Letter to Shenzhen Fumot Vaping Technology Co., Ltd. (Nov. 16, 2022) (available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/shenzhen-fumot-technology-co-ltd-645183-11162022).

[35] Warning Letter to HQD (July 20, 2020) (available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hqd-tech-usa-llc-608631-07202020).

[36] Import Alert 98-06 (Sept. 12, 2023) (available at https://www.accessdata.fda.gov/cms_ia/importalert_1163.html).

[37] *Id.*

[38] FDA Seeks Fines Against 22 Retailers for Selling Illegal Youth-Appealing E-Cigarettes, FDA News Release (Sept. 28, 2023) (available at https://www.fda.gov/news-events/press-announcements/fda-seeks-fines-against-22-retailers-selling-illegal-youth-appealing-e-cigarettes).

V. Defendants' FDV Products Have Taken Sales and Market Share from Lawful, Tobacco-Flavored Products Like NJOY ACE and NJOY Daily

98. Since 2020, FDVs, including the Defendants' products, have obtained a significant portion of the market share and sales of these products have increased drastically. During the same time period, the market share and sales volume for tobacco-flavored vapor products, such as the lawful products manufactured and sold by Plaintiff, have fallen significantly. So too have the market share and sales of refillable, pod-based products like NJOY Ace.

99. One study that analyzed retail scanner data from January 26, 2020 to December 25, 2022, found that unit shares of tobacco-flavored products decreased from 28.4% to 20.1% during this period, while unit shares for flavored products (other than mint) increased from 29.2% to 41.3%.[39] The same study also found that the market share for prefilled, pod-based products such as NJOY ACE decreased from 75.2% to 48.0%, while the market share for disposable e-cigarettes like the Defendants' FDVs increased from 24.7% to 51 .8%.[40]

100. In addition, sales data for the 4-week period ending December 25, 2022, showed that two of the top five selling e-cigarette brands were Elf Bar and Breeze—FDVs that Defendants have manufactured, marketed, distributed, and sold.[41] And surveillance conducted by FDA during the first half of 2023 "helped FDA to identify

[39] E-cigarette Unit Sales by Product and Flavor Type, and Top-Selling Brands, United States, 2020-2022, Morbidity & Mortality Weekly Rpt. (Centers for Disease Control and Prevention) (Jun. 23, 2023) (available at www.cdc.gov/mmwr/volumes/72/wr/mm7225a1.htm?s_cid=mm7225a1_w). This data only includes sales from brick-and-mortar retailers, and data reflecting sales from online retailers and tobacco specialty stores were not included.

[40] *Id.*

[41] *Id.*

Elf Bar and Esco Bar as being among the most popular brands in the United States."[42]

101. Market data also shows that FDVs have a significant share of the market in California, which again was obtained at the expense of tobacco-flavored and refillable, pod-based products. For example, sales data from California retailers for the period of February 23, 2020 to October 30, 2022 showed that sales of tobacco-flavored e-cigarettes declined by 23.5% over this time period.[43] The same data showed that the unit share at California retailers for prefilled products like NJOY Ace fell from 62.7% to 54.4% during this period, while the unit share for disposable products like FDVs increased from 37.1% to 45.4%.[44]

VI. Defendants Manufactured, Marketed, Distributed, and Sold FDVs That Were Falsely and Misleadingly Marketed As Lawful Products

102. Defendants manufacture, market, distribute, and/or sell brands of FDV products that have been and continue to be sold unlawfully in California.

103. Upon information and belief, the Elf Bar Defendants manufacture, market distribute, and sell Elf Bar, EB, EB Create, and EB Design products, which are unlawfully sold in California, or have engaged in such conduct in the past.

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[42] FDA Inspection Blitz Leads to More Than 180 Warning Letters to Retailers for the Illegal Sale of Youth-Appealing Elf Bar and Esco Bars E-Cigarettes, FDA News Release (June 22, 2023) (available at https://www.fda.gov/news-events/press-announcements/fda-inspection-blitz-leads-more-180-warning-letters-retailers-illegal-sale-youth-appealing-elf-bar); *see also id.* (noting Centers for Disease Control study that "found Elf Bar was the most popular e-cigarette sold in the U.S. in 2022").

[43] Monitoring U.S. E-Cigarette Sales: State Trends at Figure 1, CDC Foundation (Oct. 2022) (available at https://www.cdcfoundation.org/State-E-CigaretteSales-DataBrief-2022-Octo30?inline). This sales data did not include sales from vape shops or online retailers. *Id.*

[44] Monitoring U.S. E-Cigarette Sales: State Trends at Figure 2, CDC Foundation (Oct. 2022) (available at https://www.cdcfoundation.org/State-E-CigaretteSales-DataBrief-2022-Octo30?inline).

104. The Elf Bar website, www.elfbar.com, until very recently provided information about Elf Bar FDVs.[45] The website included statements that induced consumers to believe that Elf Bar products could be legally sold under California and federal law.

105. The Elf Bar website stated, in response to a "frequently asked question," that "[t]here is no diacetyl in our products, and all our products are certified safe for use."[46] This statement conveyed to consumers that Elf Bar products have met applicable standards for safety, including those incorporated into the federal process for premarket approval.

106. The Elf Bar website also included the Elf Bar "mission statement," which explained that the Elf Bar Defendants "aim" to "uphold the highest standards of legality, economics, and ethics."[47] And, when discussing the "Lighthouses Guardian Program," the Elf Bar website stated that the Elf Bar Defendants "support strong laws and regulations that forbid minors from buying and using our products" and "ELFBAR products will be closely regulated to prevent misuse."[48] These statements misrepresented to consumers that Elf Bar products are marketed and sold in compliance with state and federal law.

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[45] The Elf Bar website was publicly accessible until at least September 19, 2023. Shortly thereafter, the Elf Bar Defendants appear to have taken the website offline. The website as it existed on September 19, 2023 is available via the Internet Archive links referenced below.

[46] Elf Bar archived website available at (https://web.archive.org/web/20230919183102/https://www.elfbar.com/support.html).

[47] Elf Bar archived website (available at https://web.archive.org/web/20230802001637/https://www.elfbar.com/esg.html).

[48] Elf Bar archived website (available at https://web.archive.org/web/20230919183957/https://www.elfbar.com/minor-protection.html).

107. Elf Bar product packaging includes the statement: "Sale only allowed in the United States." This statement is false on its face because sales of Elf Bar products are not allowed in the United States. Additionally, in combination with other items on the product packaging, including FDA-mandated and California-mandated warning statements, the product packaging conveys to consumers that the products may be sold legally in the United States and specifically in California.

108. Upon information and belief, the Elf Bar Defendants rebranded Elf Bar products and currently manufacture, market, distribute, and sell EB, EB Create, and EB Design products that are unlawfully sold in California. The website for these products, https://ebdesigndisposablevape.com/, provides information about EB and EB Design products and induces consumers to believe that these products may be legally sold under California and federal law.

109. Upon information and belief, Shenzhen Han manufactures, markets, distributes, and sells Lost Mary FDVs that are sold in California. The "Lost Mary Vape Official Site" provides information online about Lost Mary products and induces consumers to believe that these products may be legally sold under California and federal law. The website, for example, claims that Lost Mary products "adhere to the highest industry standards and regulations" and are "safe, reliable, and of the utmost quality."[49]

110. Upon information and belief, Shikai Technology and Breeze Smoke manufacture, market, distribute, and sell Breeze FDVs that are unlawfully sold in California.

111. The Breeze Smoke website, www.breezesmoke.com, provides information about Breeze FDVs. The website includes statements that induce consumers to believe that these products may be legally sold under California and federal law.

[49] https://lostmaryofficialsite.com/about/.

112. The Breeze website states that "[w]e support and comply with all federal and state regulations to prevent sales to minors."[50] The website further states that "[w]e support the FDA's commitment to leverage its authority and resources to take additional steps to address these new, emerging issues associated with underage use. We are committed to being part of the solution and understand that the most important way we can make sure kids don't use any tobacco products is to limit access and appeal."[51] These statements misrepresent to consumers that Breeze products are marketed, distributed, and sold in compliance with state and federal law.

113. Breeze product packaging includes the statement: "Sale only allowed in the United States." This statement is false on its face because sales of Breeze products are not allowed in the United States. Additionally, in combination with other items on the product packaging, including FDA-mandated and California-mandated warning statements, the product packaging conveys to consumers that the products may be sold legally in the United States and in California specifically.

114. Upon information and belief, the Hyde Defendants manufacture, market, distribute, and sell Hyde FDVs that are unlawfully sold in California.

115. Hyde's website falsely suggests that these products can be lawfully sold in California and the United States. For example, rather than disclosing that FDA has sent warning letters stating that Hyde products had been misbranded and could not be marketed, distributed, or sold, the Hyde website claims that these products have "become very popular nationwide due to the incredible selection of flavors available in its vast array of disposable devices."[52]

[50] https://www.breezesmoke.com/minors-use-prevention.

[51] *Id.*

[52] https://hydevape.us.com/.

116. Upon information and belief, Defendants Shenzhen Innokin, Funyin Electronic, Pingray, Pastel Cartel, AVC, and Affiliated Imports manufacture, market, distribute, and sell Esco Bar brand FDVs that are unlawfully sold in California.

117. The Esco Bar website, www.escobars.com, operated by Pastel Cartel, provides information about Esco Bar products and makes those products available for sale. The website includes statements that induce consumers to believe that Esco Bar products may be legally sold under California and federal law.

118. As of September 25, 2023, a wide range of Esco Bar FDVs was available for purchase on www.escobars.com, including for example Esco Bars Mesh 5% 2500 Puff - Cotton Candy, Esco Bars 5% 6000 Puff – Bubbleberry and Esco Bars 5% 6000 Puff - Sour Candy Apple, suggesting to consumers that the products may be legally sold and are in compliance with FDA regulations and federal law.

119. In addition, the Esco Bar website includes an "FDA Disclaimer" that says "[t]he statements made regarding these products have not been evaluated by the Food and Drug Administration. The efficacy of these products has not been confirmed by FDA-approved research. These products are not intended to diagnose, treat, cure, or prevent any disease. All information presented here is for informational and educational purposes only and is not meant as a substitute for or alternative to information from health care practitioners. You should not combine the use of products from our site with any other medications, drugs, or alcohol. Please consult your health care professional about potential drug interactions or other possible complications before using any product. The Federal Food, Drug and Cosmetic Act requires this notice."[53]

[53] https://escobars.com/terms-conditions.

120. The Esco Bar website states further that "Esco Bars is committed to youth prevention, implementing a secured, industry-leading age verification system powered by AgeChecker.net to verify every order placed on our website. Our team continually work hard to strengthen the age verification process and improve our checkout procedure to restrict underage purchases."[54] It also states that "[a]ll of our products are sourced responsibly, independently tested for purity and potency, and are used personally by members of our staff."[55]

121. These statements misrepresent to consumers that Esco Bar products are marketed and sold in compliance with state and federal law.

122. Esco Bar product packaging includes the statement: "Sale only allowed in the United States." This statement is false on its face because sales of Esco Bar products are not allowed in the United States. Additionally, in combination with other items on the product packaging, including FDA-mandated and California-mandated warning statements, the product packaging conveys to consumers that the products may be sold legally in the United States and in California specifically.

123. Upon information and belief, Defendant King Distribution manufactures, markets, distributes, and sells Lava FDV products that are unlawfully sold in California.

124. The Lava website, www.lavapods.com, provides information about Lava FDVs and makes the products available for sale. The website includes statements that induce consumers to believe that Lava products may be legally sold under California and federal law.

125. The Lava website states that "[t]he U.S. Food and Drug Administration's (FDA) recent guidance that restricts flavored cartridges provides an opportunity for flavors to return to the market once cleared by the FDA

[54] https://escobars.com/age-policy.

[55] https://escobars.com/about-us/.

application process. Applications are due to FDA by May 12, 2020. Lava is working on submitting its application for Lava Pre-filled Pods and is well positioned to complete applications for its entire portfolio by the May deadline. Once review is completed, FDA will then determine if the flavors are able to return to market."[56] As of September 25, 2023, the "entire portfolio" of Lava products was available for purchase on www.lavapods.com, suggesting to consumers that King Distribution has completed the referenced FDA application process and its FDV products can be legally sold.

126. The Lava website also states that "[w]e are adjusting our business in light of recent federal and state restrictions on flavored vaping products."[57] As of September 25, 2023, the portfolio of Lava products available for purchase on www.lavapods.com included a wide range of FDVs in various flavors, suggesting to consumers that the products could be legally sold and that King Distribution has completed the referenced "business adjustments" necessary to comply with "recent federal and state restrictions."

127. These statements misrepresent to consumers that Lava products are marketed and sold in compliance with state and federal law.

128. Upon information and belief, Defendant HQD manufactures, markets, distributes, and sells HQD products that are unlawfully sold in California.

129. The HQD website, www.hqdtechusa.com, provides information about HQD brand FDVs and makes the products available for sale. The website includes statements that induce consumers to believe that HQD products may be legally sold under California and federal law.

130. The HQD website states that "HQD understands the importance of compliance with the PACT Act and other laws and regulations governing the sale of

[56] https://lavapods.com/flavor-restrictions.

[57] *Id.*

tobacco and electronic cigarettes. We are committed to providing our customers with high-quality products while adhering to all applicable laws and regulations."[58] This statement, alone and in combination with other statements on the website, falsely and misleadingly suggests to consumers that HQD products are sold in compliance with federal and state law.

131. The HQD website states that "HQD TECH USA is aligned with the FDA's efforts to protect America's adolescents and believes it to be an essential industry priority. It is for this reason HQD TECH USA takes youth prevention very seriously and has put into action several preventative measures including an age verification technology service to review all submitted information for purchases on the HQD TECH USA website in order to restrict anyone under 21 years of age from attempting to complete a transaction that would end in obtaining HQD TECH USA products."[59]

132. The HQD website also states that "HQD TECH USA actively follows all FDA compliance regulations in regard to packaging and labeling."[60] As of September 25, 2023, the HQD products available for purchase on www.hqdtechusa.com included a wide range of FDVs in various flavors, suggesting to consumers that HQD products can be sold without violating FDA policy and federal law.

133. Upon information and belief, Defendant The Loon manufactures, markets, distributes, and sells Loon Maxx, Loon Air+, Pluto Bars, Juicebox, King Pluto Enzo, and King Pluto Due brand products that are unlawfully sold in California.

[58] https://hqdtechusa.com.

[59] https://hqdtechusa.com/pages/youth-prevention.

[60] *Id.*

134. The Loon's website provides information about The Loon's FDVs and makes the products available for sale.[61] The website includes statements that induce consumers to believe that these products may be legally sold under California and federal law.

135. The Loon's website states that "[t]he brand was founded in 2013 and has continued to serve as a pioneer and thought leader in the vaping category. The Loon is the finest independent vaping company in the U.S. and is a leader in the revolution against combustible cigarettes."[62] On August 8, 2021, FDA sent a warning letter to The Loon to inform the company that e-cigarettes, including products on the Loon's website, could not be lawfully sold without first receiving premarket authorization as required by the Tobacco Control Act.

136. The Loon's website continues to market and sell FDVs that are not authorized and makes no mention that these products were the subject of an FDA warning letter. Instead, The Loon's website suggests that there are no legal impediments to the sale or purchase of The Loon's products, telling consumers that The Loon seeks to "satisfy the nation's vaping needs" and "offers a range of electronic nicotine products for adult smokers and vapers."[63]

137. These statements misrepresent to consumers that The Loon's products are marketed and sold in compliance with state and federal law.

138. Upon information and belief, Defendant BFL Metal Production manufactures, markets, distributes, and sells Fume and LD brand FDV products that are unlawfully sold in California.

[61] https://loonvapes.com/.

[62] *Id.*

[63] *Id.*

139. BFL Metal Production's website provides information about the company's FDVs and makes the products available for sale.[64] The website includes statements that induce consumers to believe that Fume and LD products may be legally sold under California and federal law.

140. BFL Metal Production's website says that the company is "one of the biggest manufacturer[s] of E-Cigs in the world," "one of the first manufacturers of electronic cigarettes in the world," and "a world leader in the design, manufacturing, and branding of electronic cigarettes."[65] The website states further that Fume and LD products have been highly successful because of the company's "extensive market research and development before a product ever sees the market."[66] The company also states that its products are "[n]ot for sale to minors" and claims to be "committed to preventing illegal sales to minors."[67] BFL Metal Production's website, however, does not explain that Fume and LD FDVs have not been authorized by FDA and cannot be lawfully sold in California.[68]

141. Fume product packaging includes the statement: "Sale only allowed in the USA." This statement is false on its face because sales of Fume products are not allowed in the United States. Additionally, in combination with other items on the product packaging, including FDA-mandated and California-mandated warning statements, the product packaging conveys to consumers that the products may be sold legally in the United States and in California specifically.

[64] https://www.fumevapors.com/about-us/.

[65] *Id.*

[66] *Id.*

[67] *Id.*

[68] *See id.*

142. Upon information and belief, Defendant Dongguan Hengtai d/b/a Mr. Fog manufactures, markets, distributes, and sells Mr. Fog FDVs that are unlawfully sold in California.

143. Mr. Fog's website provides information about Mr. Fog's FDVs and makes the products available for sale.[69] The website includes statements that induce consumers to believe that Mr. Fog products may be legally sold under California and federal law.

144. Mr. Fog's website states generally that the company "compl[ies] with policies." According to the website, when "[f]aced with different policy requirements in different markets, MR FOG is not afraid of high requirements such as funds and quality, and submits a series of products to better standardize products and achieve compliant supply."[70] In addition, although the website states that Mr. Fog "e-liquid products have not been evaluated by the Food and Drug Administration," it does not disclose that the products are unlawful under California law and the subject of FDA enforcement actions.[71] Instead, it says that these products "are intended for use by adults of legal smoking age."[72]

145. As of September 25, 2023, the Mr. Fog products available for purchase on the Mr. Fog website included a wide range of FDVs in various flavors, suggesting to consumers that the products are sold in a way that complies with FDA policy and federal law.[73]

[69] https://www.mrfog.com/switch-disposable/?f=nav.

[70] https://www.mrfog.com/about-us/.

[71] *Id.*

[72] *Id.*

[73] https://www.mrfog.com/switch-disposable/?f=nav.

146. Upon information and belief, Defendants Flumgio and Shenzhen PD manufacture, market, distribute, and sell Flum brand FDVs, including Flum Float, Flum Gio, and Flum Pebble, which are unlawfully sold in California.

147. The Flum website provides information about Flum FDVs and communicates that the products available for sale.[74] The website includes statements that induce consumers to believe that Flum products may be legally sold under California and federal law.

148. The Flum website displays an FDA-mandated nicotine warning and states that the products use "food graded materials."[75] The website also states that Flum products are "[n]ot for sale to minors" and includes a California Proposition 65 Warning.[76] The website, however, does not explain that Flum FDVs have not been authorized by FDA and cannot be lawfully sold in California.

149. Flum packaging includes the statement: "Sale only allowed in the USA." This statement is false on its face because sales of Flum products are not allowed in the United States. Additionally, in combination with other items on the product packaging, including FDA-mandated and California-mandated warning statements, the product packaging conveys to consumers that the products may be sold legally in the United States and in California specifically.

150. Upon information and belief, Defendants Shenzhen Daosen, EVO Brands, and PVG2 manufacture, market, distribute, and sell Puff Bar products, which are unlawfully sold in California, or have engaged in such conduct in the past.

151. The Puff Bar website, which Defendant PVG2 appears to operate, misleadingly suggests that these products may be lawfully sold, claiming that "Puff Bar provides adults with premium products to elevate life's greatest moments" and

[74] https://www.flumgio.com/.

[75] https://www.flumgio.com/pebble/.

[76] https://www.flumgio.com/disclaimer/.

that, "[f]or us, offering consumers the best choice on the market isn't just a mission—it's a requirement."[77]

152. Upon information and belief, Defendant Shenzhen Fumot manufactures, markets, distributes, and sells Fumot and RandM brand FDVs, which are unlawfully sold in California.

153. Defendant Shenzhen Fumot markets, distributes, and sells FDVs on its website, www.randm-shop.online. This website includes statements that induce consumers to believe that Flum products may be legally sold under California and federal law. Shenzen Fumot claims, for example, that the company's "vapes have become the mainstream of the Vaporizer market" and "can be shipped to the United States."[78]

154. Defendants Flawless Vape Shop and Flawless Vape Wholesale & Distribution market, distribute, and sell numerous brands of FDVs to consumers in California and across the country, including from the website www.flawlessvapeshop.com. Defendants Flawless Vape Shop and Flawless Vape Wholesale & Distribution make statements on this website that induce consumers to believe that FDVs can be legally sold under California and federal law.

155. The Flawless Vape Shop website states that "[w]e aim to deliver only the highest quality products."[79] The website explains further that the FDVs "sold on this site [are] intended for adult smokers."[80] The website also displays a map that shows that Flawless Vape Shop and Flawless Vape Wholesale & Distribution will sell and ship products to almost every state, including California, and includes a

[77] https://puffbar.com/.

[78] https://www.randm-shop.online/pages/about-randmvape.

[79] https://www.flawlessvapeshop.com/.

[80] *Id*.

California Proposition 65 Warning.[81] The website, however, does not explain that the FDVs it sells have not been authorized by FDA and cannot be lawfully sold in California.

156. Defendant Price Point markets, distributes, and sells numerous brands of FDVs to consumers in California and across the country, including from the website www.pricepointny.com. Defendant Price Point makes statements on this website that induce consumers to believe FDVs can be legally sold under California and federal law.

157. Defendant Price Point's website states that "[w]e understand the concern of buying tobacco products on the internet" and therefore "tak[e] the necessary steps to keep our devices out of the wrong hands." https://www.pricepointny.com/pages/service-desk. In addition, the website states that FDVs "are intended for use by persons 18 or older" and includes a California Proposition 65 Warning.[82] But it does not explain that the FDVs it sells have not been authorized by FDA and cannot be lawfully sold in California.

158. Defendant Mi-One markets, distributes, and sells numerous brands of FDVs to consumers in California and across the country, including from the website https://www.mipod.com. Defendant Mi-One makes statements on its website that induce consumers to believe FDVs can be legally sold under California and federal law.

159. Defendant Mi-One describes itself as "a master distributor for the top brands in the vaping industry like Lost Mary and EBCreate"[83] and claims to "put the customer first and commit to excellence in everything we do."[84] The Mi-One

[81] *Id.*

[82] *Id.*

[83] https://mipod.com/collections/disposable-vape.

[84] https://mipod.com/pages/our-values.

website states further that FDVs "are an increasingly popular way to vape" and explains that the website "carries the best names in the industry."[85] The website includes an "FDA Disclaimer" that states, among other things, that "[t]he efficacy of these products and the testimonials made have not been confirmed by FDA-approved research."[86] It also offers "[f]ree shipping valid for most of the 48 continuous U.S. States."[87] The website, however, does not explain that the FDVs it sells have not been authorized by FDA and cannot be lawfully sold in California.

160. Defendant Element Vape markets, distributes, and sells numerous brands of FDVs to consumers in California and across the country, including from the website www.elementvape.com. Defendant Element Vape makes statements on its website that induce consumers to believe FDVs can be legally sold under California and federal law.

161. Defendant Element Vape's website states that FDVs "sold on this site [are] intended for adult smokers." [88] The website states further that the company will ship FDVs to customers throughout the United States, including to California.[89] The website also includes an FDA disclaimer, which provides that "statements made regarding these products have not been evaluated by the Food and Drug Administration," and a California Proposition 65 Warning.[90] But the website does not explain that the FDVs it sells have not been authorized by FDA and cannot be lawfully sold in California.

[85] https://mipod.com/collections/disposable-vape.

[86] https://mipod.com/pages/fda-disclaimer.

[87] https://mipod.com/policies/shipping-policy.

[88] https://www.elementvape.com/.

[89] https://www.elementvape.com/shipping-and-handling.

[90] https://www.elementvape.com/.

162. Defendant Vape Sourcing markets, distributes, and sells numerous brands of FDVs to consumers in California and across the country, including from the website www.vapesourcing.com. Defendant Vape Sourcing makes statements on its website that induce consumers to believe FDVs can be legally sold under California and federal law.

163. Defendant Vape Sourcing's website states that the company "is a professional vape shop online aimed at USA market. We devote to provide valued customers with high-quality and various e-cigarettes at best price from the regular source. Vapesourcing has [an] experienced and professional team who rigorously screens, tests and sources from all major e-cigarette brands on a daily basis to provide vapors around the world with good products that we really know."[91] The website states further that FDVs "sold on this website are intended for adult smokers" are includes a California Proposition 65 Warning.[92] But the website does not explain that the FDVs it sells have not been authorized by FDA and cannot be lawfully sold in California.

VII. The PACT Act Imposes Additional Requirements on Delivery Sales of FDVs

164. The federal Prevent All Cigarette Trafficking Act, 15 U.S.C. § 375 *et seq*. ("PACT Act"), regulates the delivery sale of FDVs into all states, including California. *Id.* § 375(2) (including "electronic nicotine delivery systems," or FDVs, in the definition of "cigarette"). A delivery sale is any sale for which "the seller is otherwise not in the physical presence of the buyer when the request for purchase or order is made." *Id.* § 375(5).

165. The PACT Act requires that all delivery sellers verify each customer's age by obtaining their full name, date of birth, and residential address using certain

[91] https://vapesourcing.com/about-us.

[92] https://vapesourcing.com/disposable-pod.html.

commercially available databases. *Id.* § 376a(b)(4). Upon information and belief, Defendants have engaged and continue to engage in business with distributors and retailers that they knew, or should have known, make delivery sales of FDVs into California without satisfying these age-verification requirements, or make such sales themselves without satisfying these age-verification requirements.

166. The PACT Act requires that a person selling, transferring, shipping for profit, advertising, or offering FDVs for sale into a state that taxes the sale of those products (a) register with the U.S. Attorney General and the tobacco tax administrator of the state; and (b) on the tenth day of each month, file with the state tobacco tax administrator a memorandum or copy of the invoice covering the previous month's shipment of FDVs. *See id.* § 376(a)(1)-(2). Upon information and belief, Defendants engaged and continue to engage in business with distributors and retailers that they knew, or should have known, make delivery sales of FDVs into California without satisfying these registration and filing requirements, and Defendants themselves distribute such products without satisfying these registration and filing requirements.

167. The PACT Act requires that all delivery sellers create and maintain detailed records of each delivery sale until the end of the fourth full calendar year beginning after the date of that delivery sale, and to make the records available to the federal government, state and local tobacco tax administrators, and the state attorneys general. *Id.* § 376a(c)(3). Upon information and belief, Defendants engaged and continue to engage in business with distributors and retailers that they knew, or should have known, make delivery sales of FDVs into California without satisfying these recordkeeping requirements, or make such sales themselves without satisfying these recordkeeping requirements.

168. The PACT Act requires that all delivery sellers pay all state and local excise taxes on tobacco products, including FDVs, before shipping those products

and affix and apply tax stamps and other indicia indicating the payment of excise taxes. *Id.* § 376a(d). Upon information and belief, Defendants engaged and continue to engage in business with distributors and retailers that they knew, or should have known, make delivery sales of FDVs into California without satisfying these tax-collection requirements, and Defendants who directly sell FDVs make such sales without satisfying these tax-collection requirements.

169. The PACT Act requires that all bills of lading and shipping packages continuing FDVs be clearly marked with the following statement:

> CIGARETTES/NICOTINE/SMOKELESS TOBACCO: FEDERAL LAW REQUIRES THE PAYMENT OF ALL APPLICABLE EXCISE TAXES AND COMPLIANCE WITH APPLICABLE STATE AND LOCAL LICENSING AND TAX-STAMP OBLIGATIONS.

Id. § 376a(b). Upon information and belief, Defendants engaged and continue to engage in business with distributors and retailers that they knew, or should have known, make delivery sales of FDVs into California without satisfying these labeling requirements, and Defendants who directly sell FDVs make such sales without satisfying these labeling requirements.

170. The PACT Act requires that all delivery sales comply with all applicable state and local laws as if the delivery sale occurred entirely within the specific state or place. *Id.* § 376a(a). Upon information and belief, Defendants engaged and continue to engage in business with distributors and retailers that they knew, or should have known, make sales in violation of California law, including by failing to collect and remit applicable state taxes on sales of FDVs and by failing to submit monthly reports and invoices to the California Department of Revenue.

171. Defendants have made, and continue to make, delivery sales of FDVs that violate each of these PACT Act requirements. In addition, Defendants engaged and continue to engage in business with distributors and retailers that they knew, or should have known, violate each of these PACT Act requirements.

FIRST CLAIM FOR RELIEF

Violation of the California Unfair Competition Law (Cal. Bus. & Prof. Code § 17200, *et seq.*)

172. Plaintiff specifically realleges and incorporates herein by reference each and every allegation contained in Paragraphs 1 through 171.

173. This claim is for unfair competition under the California Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, *et seq.* ("UCL").

174. Plaintiff brings this claim against each of the Defendants identified above.

175. The UCL prohibits "unfair competition," which is broadly defined to include "any unlawful, unfair or fraudulent business act or practice." Cal. Bus. & Prof. Code § 17200.

176. Defendants have engaged in acts and practices that are unlawful, unfair, and fraudulent.

177. Defendants' conduct when manufacturing, distributing, marketing, and selling FDVs is unlawful conduct violating the UCL. This conduct is unlawful in several respects, including the following:

(a) Defendants' conduct when distributing and selling FDVs in California is contrary to California's flavor ban. Cal. Health & Safety Code § 104559.5.

(b) Defendants' conduct with respect to FDVs violated and continues to violate California's Consumer Legal Remedies Act, which makes it unlawful to "[m]isrepresent[] the source, sponsorship, approval, or certification of goods" or to "[r]epresent[] that goods . . . have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have." Cal. Civ. Code § 1770(2), (5).

(c) Defendants violated and continues to violate the federal PACT Act by (1) failing to comply with California laws generally applicable to sales of cigarettes, including e-cigarettes, (ii) failing to comply with shipping package and other labeling requirements, (iii) failing to comply with age verification requirements, and/or (iv) failing to register with the Attorney General of the United States and with the State and to file monthly reports. *See* 15 U.S.C. § 376a(a).

178. Defendants' conduct when manufacturing, distributing, marketing, and selling FDVs is unfair conduct that violates the UCL and threatens competition. Defendants' conduct has undermined and continues to undermine the state's policy against the sale of products other than those that are tobacco-flavored. It is also contrary to FDA regulatory requirements and the agency's many warning letters and actions making clear that Defendants' products are misbranded and cannot be sold or distributed.

179. Defendants' conduct allows and encourages consumers to purchase products that law-abiding manufacturers cannot sell while diverting them away from lawful products that satisfy regulatory requirements. Defendants' conduct thereby creates an unfair marketplace. Companies that abide by state law, seek and obtain premarket approval, and abide by significant restrictions are forced to compete with companies that openly eschew state law and regulatory requirements and flout the FDA's clear direction not to market, distribute, or sell their specific products.

180. Defendants' conduct when manufacturing, distributing, marketing, and selling FDVs has been and continues to be fraudulent conduct that violates the UCL. Defendants made express and implied statements on their websites, on packaging, and in advertisements stating and suggesting that their FDV products were lawful products. These express and implied statements were fraudulent and misleading because none of the Defendants' FDV products can be lawfully sold in California

specifically and because FDA has made expressly clear through warning letters and other actions that these products have been misbranded and should not be marketed, sold, or distributed in the United States. Defendants fail to disclose this material information when marketing, distributing, and selling FDVs.

181. Defendants' unfair competition actually and proximately caused Plaintiff to lose money or property. Cal. Bus. & Prof. Code § 17204. Plaintiff's claims are not based on purchases or vapor use by underage consumers. Plaintiff's claims are based on adult consumers, the adult market for e-cigarettes, and the Defendants' impact on that market. Defendants' unlawful, unfair, and fraudulent conduct placed NJOY at a competitive disadvantage because it induced lawful, adult consumers to buy illegal and fraudulently marketed FDVs, rather than legal products such as those marketed by NJOY.

182. As a direct and proximate result of the Defendants' acts of unfair competition, Defendants have wrongfully taken sales and profits from Plaintiff and deprived Plaintiff of the benefit of its substantial investment of time, effort, and resources in, among other things, developing and marketing NJOY products. Defendants should be ordered to provide restitution to Plaintiff as a consequence of their unlawful, unfair, and fraudulent activities. Defendants should further be ordered to disgorge all profits from the above conduct.

183. The unlawful, unfair, and fraudulent business acts and practices of Defendants continue to harm Plaintiff because Defendants are currently engaging in these acts and practices, which are likely to continue unless and until this Court provides relief. Accordingly, Plaintiff seeks an order enjoining Defendants from engaging in the acts and practices alleged above. In addition, Plaintiff seeks recovery of attorney's fees, costs and expenses incurred in the filing and prosecution of this action.

SECOND CLAIM FOR RELIEF

Violation of the California False Advertising Law (Cal. Bus. & Prof. Code § 17500, *et seq.*)

184. Plaintiff specifically realleges and incorporates herein by reference each and every allegation contained in Paragraphs 1 through 171.

185. This claim is for false and misleading advertising under the California False Advertising Law, Cal. Bus. & Prof. Code § 17500, *et seq.* ("FAL").

186. Plaintiff brings this claim against each of the Defendants identified above.

187. Defendants disseminated advertising before the public and consumers in California that: (a) contains one or more statements that are deceptive, untrue, and misleading; (b) Defendants knew, or in the exercise of reasonable care should have known, are deceptive, untrue, and misleading; (c) concern the sale of a product; and (d) are likely to mislead or deceive a reasonable consumer.

188. Defendants made express and implied statements on their websites, on packaging, and in advertisements that their FDV products were lawful products. These express and implied statements were fraudulent and misleading because none of the Defendants' FDV products can be lawfully sold in California and because FDA has made expressly clear through warning letters and other actions that they should not be sold in the United States. Defendants failed to disclose this material information when distributing, marketing, and selling FDVs.

189. As a direct and proximate result of the Defendants' deceptive, false, and misleading advertising, Defendants have wrongfully taken Plaintiff's profits and deprived Plaintiff of the benefit of its substantial investment of time, effort, and resources in, among other things, developing and marketing NJOY products. Defendants should be ordered to provide restitution to Plaintiff as a consequence of

Defendant's unlawful, unfair, and fraudulent activities. Defendants should further be ordered to disgorge all profits from the above conduct.

190. Defendants are currently engaged in false and misleading advertising, which is likely to continue unless and until this Court provides relief. Accordingly, Plaintiff seeks an order enjoining defendants from engaging in such conduct. In addition, Plaintiff seeks recovery of attorney's fees, costs and expenses incurred in the filing and prosecution of this action.

THIRD CLAIM FOR RELIEF

False Advertising in Violation of Section 43(a) of the Lanham Act (15 U.S.C. § 1125(a))

191. Plaintiff specifically realleges and incorporates herein by reference each and every allegation contained in Paragraphs 1 through 171.

192. This cause of action is for false advertising under the federal Lanham Act, 15 U.S.C. § 1125(a).

193. Plaintiff brings this claim against each of the Defendants identified above.

194. Defendants have made false and misleading statements in commercial communications and advertisements concerning their FDV products in violation of the Lanham Act.

195. Defendants' statements were literally false and/or likely to deceive a substantial portion of the relevant purchasing public as to the nature, characteristics, and qualities of the Defendants' products and commercial activities. The relevant purchasing public is comprised of consumers who are old enough to lawfully purchase e-cigarettes and vapor products.

196. Defendants made express and implied statements on their websites, on packaging, and in advertisements that their FDV products were lawful products. These express and implied statements were fraudulent and misleading because none

of the Defendants' FDV products can be sold in California and because FDA has made it expressly clear through warning letters and other actions that these specific products cannot be sold in the United States. Defendants failed to disclose this material information when manufacturing, distributing, marketing, and selling FDVs.

197. Defendants' conduct has a tendency to deceive, and actually has deceived, a material segment of the persons to whom Defendants directed their marketing activities. Defendants' false and misleading statements are material in that they are likely to influence adult vapor consumers to purchase the Defendants' products under the mistaken belief that those products were lawful products that can be sold in California and permitted under federal law and by federal regulators. Defendants' acts as described herein constitute unfair competition.

198. As a proximate and direct result of these false and misleading statements, consumers were deceived into believing that the Defendants' FDVs were lawful products and purchased FDVs instead of lawful products such as NJOY. Defendants' false and misleading statements have resulted in fewer sales of NJOY products and the loss of current and prospective customers who, but for the Defendants' conduct, would have done business with Plaintiff.

199. Plaintiff has been, and absent injunctive relief will continue to be, irreparably harmed by the Defendants' actions.

200. Plaintiff is also entitled to damages, trebled, and attorneys' fees and costs as a result of the Defendants' willful conduct.

FOURTH CLAIM FOR RELIEF

Violation of the Prevent All Cigarette Trafficking Act of 2009 (15 U.S.C. § 375 *et seq.*)

201. Plaintiff specifically realleges and incorporates herein by reference each and every allegation contained in Paragraphs 1 through 171.

202. Defendants' conduct violates the federal PACT Act, 15 U.S.C. § 175 *et seq*., regulating the delivery sale of cigarettes, including e-cigarettes and vapor products, purchased on the internet.

203. Defendants have, among other things, (i) failed to comply with all California laws generally applicable to sales of cigarettes, including e-cigarettes, pursuant to 15 U.S.C. § 376a(a)(3); (ii) failed to comply with the shipping package and other labeling requirements pursuant to 15 U.S.C. § 376a(b); (iii) failed to comply with age verification requirements pursuant to 15 U.S.C. §§ 376a(b)(4) & (d); and (iv) failed to register with the Attorney General of the United States and with the State and file monthly reports, pursuant to 15 U.S.C. §§ 376(a)(1) & (2).

204. Defendants engaged and continue to engage in business with distributors and retailers that they knew, or should have known, make delivery sales of FDVs into California without satisfying the requirements of the PACT Act and have aided and abetted violations of the PACT Act.

205. Plaintiff is entitled to bring this action against Defendants to prevent and restrain violations of the PACT Act as a permit holder under Section 5712 of the Internal Revenue Code of 1986. *See* 15 U.S.C. § 378(d).

206. Plaintiff has no adequate remedy at law for the foregoing continuing wrongful conduct. Plaintiff has been, and absent injunctive relief will continue to be, irreparably harmed by Defendants' actions in violation of the PACT Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against Defendants as follows:

(1) That the Court preliminarily and permanently enjoin and restrain Defendants, its officers, directors, agents, employees and all persons and entities in active concert or participation with it, from doing, abiding, causing, or abetting any of the following:

(a) marketing, distributing for sale, or selling any flavored disposable vapor products in California that violate the State's flavor ban;

(b) importing, marketing, distributing for sale, or selling in the United States any flavored disposable vapor products;

(c) making false and misleading statements when selling, offering for sale, promoting, advertising, marketing, or distributing FDV products;

(d) competing unfairly with Plaintiff in any other manner;

(2) That the Court Order Defendants to provide appropriate restitution for harm suffered by Plaintiff as a result of Defendants' unfair competition.

(3) That the Court Order Defendants to account for and pay over to Plaintiff all profits received by Defendants from its unlawful, unfair, and fraudulent acts.

(4) That the Court Order Defendants to account for and pay Plaintiff damages to which Plaintiff is entitled as a result of the Defendants' false and misleading statements in violation of the Lanham Act.

(5) That the Court treble such damages because of Defendants' willful actions.

(6) That the Court award Plaintiff actual, compensatory, incidental, and consequential damages.

(7) That the Court award Plaintiff enhanced, treble, and/or punitive damages.

(8) That the Court award Plaintiff reasonable attorneys' fees and the costs of this action.

(10) That the Court grant Plaintiff such other relief as is just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all triable issues of fact.

Dated: October 19, 2023

Respectfully submitted,

/s/ Lauren S. Wulfe

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