UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORKx	
THE CITY OF NEW YORK,	
Plaintiff,	
-against-	Civil Action No. 23-5880 (LLS)
MAGELLAN TECHNOLOGY, INC., ECTO WORLD, LLC, d/b/a Demand Vape, MATTHEW J. GLAUSER, DONALD HASHAGEN, MAHANT KRUPA 56 LLC d/b/a Empire Vape Distributors, NIKUNJ PATEL, DEVANG KOYA, STAR VAPE CORP., NABIL HASSEN, DORBES, LLC, d/b/a Hydevapeofficial.com, CHRISTIAN A. SMITH,	
Defendants.	
x	

MEMORANDUM OF LAW OF PLAINTIFF THE CITY OF NEW YORK IN SUPPORT OF A PRELIMINARY INJUNCTION PURSUANT TO F. R. CIV. P. 65

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Plaintiff the City of New York (the "City") respectfully submits this memorandum of law in support of its motion to preliminarily enjoin under Fed. R. Civ. P. 65 defendants Magellan Technology, Inc., Ecto World, LLC d/b/a Demand Vape, Matthew J. Glauser, Donald Hashagen, Mahant Krupa 56 LLC d/b/a Empire Vape Distributors, Nikunj Patel, and Devang Koya (when referred to collectively, "Defendants") from violating New York City Administrative Code § 17-715 and/or causing or contributing to a public nuisance through transactions with flavored nicotine products in or into New York City. ¹

PRELIMINARY STATEMENT

In defiance of multiple federal statutes, multiple New York State statutes, and multiple New York City Administrative Code provisions, Defendants distribute, sell, offer for sale, possess with intent to sell or possess with intent to offer for sale in or into New York City electronic cigarettes, (a/k/a "e-cigarettes," "electronic nicotine delivery systems" or "vapes"). E-cigarettes are devices using batteries to heat nicotine solutions ("e-liquids") to yield nicotine-infused mists or vapors inhaled by the user (a "vaper") instead of the burning tobacco smoke produced by conventional cigarettes. So flagrant is Defendants' law-breaking that Magellan-Demand Vape's owner publicly admits "most importantly, [to] ensur[ing] that retailers across New York can offer" flavored e-cigarettes² – despite the plain prohibition against sales enacted under federal, State and New York City law.

¹ Defendants Star Vape Corp., Nabil Hassen, Dorbes LLC, d/b/a Hydevapeofficial.com, and Christian A. Smith have reached settlements in principle with the City and no relief is sought against those defendants.

²https://www.nydailynews.com/2023/10/07/eric-adams-unfair-attack-on-vaping-nyc-lawsuit-against-legal-companies-is-wrong/

The nicotine-laced e-liquids in e-cigarettes can be (and are) flavored to taste of tobacco but Defendants choose to sell predominantly e-cigarettes whose vapors taste of exotic fruit, candy, soda, or desserts know to attract children, notwithstanding that "tobacco-flavored e-cigarette products and devices, ... are the only e-cigarettes that currently may be lawfully sold or distributed in the U.S." E-cigarettes have generated intense concern among public health authorities, the medical community, and the parents of teen-age children because flavored, high-nicotine e-cigarettes are documented as enormously attractive to youth at the same time that "[s]cientific evidence clearly establishes that nicotine is highly addictive, causes a heightened risk of cardiovascular defects, and hinders brain development in humans under the age of twenty-five." City of Chicago v. Equite LLC, 2023 U.S. Dist. LEXIS 169995, at *6-7 (N.D. Ill. Sep. 19, 2023).

Despite that, e-cigarettes have "rapidly become popular – especially among young people, who have overwhelmingly adopted flavored [vapes] as their tobacco products of choice." *Magellan Tech., Inc. v. United States FDA*, 70 F.4th 622, 625 (2d Cir. 2023). The appeal to youth can be explained by the fact that e-cigarette manufacturers intentionally design flavored e-cigarettes to attract youth by creating fruit, candy and dessert flavors, by formulating milder solutions that reduce the natural harshness of nicotine, and by boosting nicotine concentration well above that provided by conventional cigarettes. *See City of Chicago*, 2023 U.S. Dist. LEXIS

https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-two-vuse-solo-menthol-e-cigarette-products. The City makes no direct claims under the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009), codified at 21 U.S.C. § 387 et seq. (the "Tobacco Control Act"), but respectfully asks that the Court take judicial notice that every single sale of every single brand of flavored e-cigarette or e-liquid by the Defendants (except tobacco flavor) is illegal everywhere in the United States under at least that statute. The Tobacco Control Act requires pre-market approval by the federal Food and Drug Administration ("FDA") before any tobacco product, including e-cigarettes, may be placed on the market. No such approvals have been obtained for any flavored nicotine product (except tobacco flavor) sold by the Defendants or any other member of the e-cigarette industry. As stated in the above-cited FDA press release, "tobacco-flavored e-cigarette products and devices, ... are the only e-cigarettes that currently may be lawfully sold or distributed in the U.S."

169995, at *6-7 ("E-cigarettes pose a particular danger because they are more efficient at delivering nicotine into the body than traditional cigarettes, and because vendors of liquid nicotine used in e-cigarettes could make their products taste like soda, candy, popcorn, or other products that might appeal to younger individuals."). By fashioning devices that dispense higher, milder doses of nicotine in a mist tasting evocatively of fruit, candy or desserts the e-cigarette industry has created a "pediatric epidemic of youth e-cigarette use" that may condemn "to a lifetime of nicotine addiction and associated health risks" the nine out of ten teenage smokers that statistics show will continue to smoke into adulthood. The recent flood of flavored e-cigarettes onto the market has skyrocketed e-cigarette use by those age twenty-five and younger, reversing a decadeslong decline in youth smoking. 5

The health emergency created by e-cigarettes has compelled every level of government to enact legislation intended to keep flavored devices out of the hands of youthful users. But despite that legislation, which provides New York City with one of the Nation's most powerful armamentariums against the introduction into the City of flavored e-cigarettes, Defendants' flouting of federal, State and City laws has left the City awash in flavored "vapes." Sixty-five per cent of a sample of New York City retailers sold flavored e-cigarettes to buyers upon request. The City issued 2,524 summonses to tobacco retailers in 2022 for violating the City's prohibitions against flavored e-cigarettes and summonses for sales of flavored e-cigarettes to persons aged less than 21 are sharply on the rise, from 35 in 2020 to 326 in 2022, and on pace to exceed the latter

⁴ See https://www.cdc.gov/tobacco/basic information/e-cigarettes/surgeon-general-advisory/index.html.

⁵ See, e.g., Cooper M, Park-Lee E, Ren C, Cornelius M, Jamal A, Cullen KA. *Notes from the Field: E-cigarette Use Among Middle and High School Students - United States*, 2022. MMWR Morb Mortal Wkly Rep. 2022 Oct 7;71(40):1283-1285. doi: 10.15585/mmwr.mm7140a3. PMID: 36201370; PMCID: PMC9541029.

⁶ See Declaration of Vincent Lesnak.

number in 2023.⁷ Observations in 2023 of hundreds of stores selling e-cigarettes in New York City revealed that the great majority had no license to do so.⁸

No flavored e-cigarette has received the pre-market approval of the federal Food and Drug Administration ("FDA") required to market those devices. *See* n. 3, *supra*. Defendant Demand Vape itself has argued that "*The public interest* … *does not favor rewarding parties that eschew federal regulatory requirements* – *like FDA premarket authorization* … ." The City now moves under the injunctive remedies available under the City's Administrative Code and its common law police powers to dismantle the flavored e-cigarette marketplace this same defendant and others help create within the City's borders.

FACTS

It is well-established that "in deciding a motion for a preliminary injunction, a court may consider the entire record including affidavits and other hearsay evidence." *Helio Logistics, Inc. v. Mehta*, 2023 U.S. Dist. LEXIS 18787 (S.D.N.Y. Feb. 3, 2023) at *6 (cleaned up).

The Public Nuisance Created by the Sale of Flavored E-Cigarettes

The facts set forth in the Declarations Meredith Berkman, Frances Daniels, Janine Hodgkins, Vincent Lesnak, Deputy Commissioner James Hurst, Mia Marais, and Deputy Commissioner Michelle Morse, M.D., briefly summarized here, establish that Defendants' illegal distribution and sale of flavored e-cigarettes has caused a public nuisance consisting of, *inter alia*, ever-increasing sales of addictive chemicals to young people, injury to health that accompanies those sales, and the proliferation of unlicensed stores selling an illegal product.

⁷ See Declaration of James Hurst.

⁸ See Declaration of Meredith Berkman.

⁹ See Declaration of Eric Proshansky (Pro. Decl.) Ex. G at 28 (emphasis added).

Declaration of Meredith Berkman

Meredith Berkman is co-founder and president of Parents Against Vaping e-cigarettes ("PAVe"), a grassroots organization formed by parent-volunteers of New York City children to combat the youth vaping epidemic. *See Declaration of Meredith Berkman ("Berkman Decl.")*. PAVe members canvassed City neighborhoods for retail outlets that display flavored e-cigarettes. From February to June 2023, approximately 60% of the 313 stores visited by PAVe volunteers displayed flavored nicotine e-cigarettes for sale. A popular brand known as "Elf Bar" was the most commonly observed. Defendant Magellan's Hyde-brand flavored e-cigarettes were also observed, identified as for sale at 7 stores in the Manhattan and the Bronx. The great majority – approximately 93% of stores displaying flavored e-cigarettes – were either completely unlicensed to sell any tobacco products at all or were unlicensed to sell e-cigarettes. *Berkman Decl.* Ex. A.

Declaration of James Hurst

James Hurst is Deputy Commissioner for Enforcement of the New York City Department of Consumer and Worker Protection ("DCWP"), with responsibility for enforcing certain of the City Administrative Code's laws regulating tobacco and e-cigarette sales. *See Declaration of James Hurst* ("Hurst Decl.").

DCWP maintains records of summonses issued in its enforcement actions, including as relevant here, for engaging in sales of e-cigarettes without a license in violation of Ad. Code § 20-561, engaging in sales of flavored e-cigarettes in violation of Ad. Code § 17-715 (b) 1, and engaging in sales of e-cigarettes to persons under the age of 21 in violation of Ad. Code § 17-706.

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Yolo Smoke City, 1173 Lexington Avenue, N.Y., N.Y. on February 23, 2023; Convenience of Columbus, 550 Columbus Avenue, N.Y., N.Y. on February 23, 2023; Morris Park Convenience Store, 1048 Morris Park Avenue, Bronx, N.Y. on March 18, 2023; Garden Fresh Gourmet Deli, 969 Morris Park Avenue, Bronx, N.Y. on March 18, 2023; Hookah 2 Plus, 750b Morris Park Avenue, Bronx, N.Y. on March 18, 2023; LA Convenience Store, 101 Avenue A, N.Y., N.Y. on April 12, 2023; XXX Vape Shop, 26 Avenue C, N.Y., N.Y. on May 1, 2023

In 2022, DCWP conducted approximately 12,400 inspections of businesses selling tobacco or electronic cigarettes and i) issued approximately 7,400 summonses for violations of Ad. Code § 20-561 for selling tobacco or electronic cigarettes without the required license; ii) issued approximately 2,524 summonses for violations of NYC Code § 17-715(b) for sales of flavored electronic cigarettes or e-liquids; and iii) issued approximately 304 adjudications of summonses issued for selling an e-cigarette to a person less than the age of 21, of which 214 occurred at unlicensed businesses. *See generally Hurst Decl*. There has been a marked increase in the number of summonses issued by DCWP for selling electronic cigarettes to an underage person. DCWP issued 35 such summonses in 2020, 171 in 2021, and 326 in 2022. From the start of the year through July 20, 2023, DCWP has already issued 208 summonses for underage sales.

Declaration of Vincent Lesnak

Cross Border Solutions LLC ("Cross Border") investigates and compiles information on the tobacco industry. Cross Border marshalled shoppers to assess the availability of flavored ecigarettes throughout New York State, including New York City. See Declaration of Vincent J. Lesnak (Lesnak Decl.) ¶ 1-2. Observations by Cross Border personnel at approximately 400 retail outlets in New York City and State revealed several hundred retail stores selling a wide variety of flavored e-cigarettes, in flavors such as watermelon ice, cotton candy, rainbow candy, fresh vanilla, pink lemonade, peach mango pineapple, strawberry watermelon bubblegum, mixed berries, guava bubble gum, blue cotton candy, cranberry grape, kiwi passion fruit guava, cherry cola, apricot nectar and more. Lesnak Decl. Ex. A.

Of 403 stores at which Cross Border shoppers attempted purchases, 268 sold a flavored ecigarette; 197 of those stores were in New York City. *Id.* Cross Border personnel either purchased or observed flavored Hyde brand e-cigarettes at 55 of the 268 stores that sold an e-cigarette, 15 of

which were in New York City. Cross Border personnel also either bought or observed flavored "Elf Bar" brand e-cigarettes, presently the most popular brand in the United States, at 146 of the 268 stores that sold an e-cigarette; of those stores, 120 were located in the City. *Id*.

Declaration of Michelle Morse, M.D.

Michelle Morse, M.D. is Deputy Commissioner and Chief Medical Officer of the City's Department of Health and Mental Hygiene and has reviewed the current scientific literature concerning the health effects of e-cigarette use by youth, especially the effect of nicotine on the developing adolescent brain. *See Declaration of Deputy Commissioner Michelle Morse* ("Morse Decl.").

Briefly stated, nicotine can change the chemistry of the adolescent brain and may affect learning ability and worsen memory and concentration. Youth are particularly vulnerable to nicotine dependence, which can occur even with non-daily, occasional use. Nicotine withdrawal symptoms include anxiety, irritability and depressed mood, so nicotine dependence may compound stress and mental health symptoms. Youth who use e-cigarettes are more likely to try conventional cigarettes, which similarly contain nicotine and remain a leading cause of death in NYC and globally.

Between 2017 and 2022, the average nicotine levels of e-cigarettes sold in the United States more than doubled, rising from 2.5% to 4.4%, with the result that the nicotine levels are double or more what is permitted throughout Europe, the United Kingdom, and Canada. Nicotine concentrations tend to be even higher in the disposable products sold by the Defendants with currently popular disposable devices in the United States (*e.g.*, Elf Bar) having nicotine content that is more than 15 times higher than typical European devices. Dozens of countries prohibit the sale of e-cigarettes altogether, from Mexico to Thailand, Egypt and India.

Declarations of Frances Daniels, Janine Hodgkins, and Mia Marais

Frances Daniels, Janine Hodgkins, and Mia Marais are New York City parents whose children, have been affected by the distribution and sale of e-cigarette and e-liquid products in the City.

Ms. Daniels has a 22-year-old, Finn, who as a freshman in college contracted E-cigarette or Vaping Use-Associated Lung Injury ("EVALI"), an inflammatory condition of the lungs thought to be caused by e-cigarettes. Because of EVALI, Finn's lungs collapsed, requiring significant surgery and a prolonged hospital stay. *See Declaration of Frances Daniels*.

Ms. Hodgkins's son was introduced to e-cigarettes in the seventh grade. That introduction turned into an addiction, and Ms. Hodgkins has noticed that her son hides to smoke, has become irritable, argumentative, and has trouble eating and sleeping. He smokes often and throughout the day. Ms. Hodgkins's son began smoking e-cigarettes in blueberry and cherry flavors. *See Declaration of Janine Hodgkins*.

Ms. Marais is a resident of lower Manhattan and a parent of children aged 10 and 14. Ms. Marais describes a common experience in New York City – the apparent marketing of e-cigarette and e-liquid products to young children by a smoke shop across the street from her apartment. Upon opening, the store displayed candy and toys along with flavored e-cigarettes and employees provided free brownies to children from the nearby school. Ms. Marais's 14-year-old son told her that the store promised to stock whatever the children wanted. *See Declaration of Mia Marais*.

Defendants' Importation, Distribution, and Sale of Flavored E-Cigarettes

The easy availability of flavored e-cigarettes to New York City youth is the result of the Defendants' importation, sale and distribution of those products. Defendants' activities are

summarized below and in the declaration and annexed exhibits of Assistant Corporation Counsel, Eric Proshansky ("*Pro. Decl.*").

Magellan Technology Inc.

Defendant Magellan Technology Inc. ("Magellan"), 2225 Kenmore Ave., Buffalo, NY 14207, owned in whole or part by defendant Matthew J. Glauser ("Glauser"), imports flavored ecigarettes into the United States from China, sold under the brand name "Hyde." *Pro. Decl.* Ex. J ¶ 4, Ex. M ¶¶ 2, 5, 6. Magellan owns the worldwide rights to the "Hyde" brand of e-cigarettes, essentially all of which are flavored, including U.S. Trademark Application No. 88920577 for the trademark "Hyde." *Pro. Decl.* Ex. K ¶¶ 16, 17. Magellan has offered Hyde electronic cigarettes for sale in U.S. commerce since at least as early as July 2019. *Id.* ¶ 19. As of December 2022, Hyde e-cigarettes were manufactured for Magellan under contract with a company in Shenzhen, China. Magellan serves as wholesaler and distributor of Hyde e-cigarettes and is the "master distributor" for all Hyde and Juno products in the United States. *Pro. Decl.* Ex. J, ¶ 4, Ex. M, ¶¶ 2, 5, 6.

Hyde's flavored e-cigarettes are known as "disposables," usually sold with a pre-filled container of a flavored nicotine e-liquid built-in to the device; the entire device is discarded once the reservoir of e-liquid has been consumed. Disposables of the type sold by Magellan are currently the most popular type of electronic cigarette on the market. *Pro. Decl.* Ex. F at 93:3-95:12; Ex. G, ¶ 49.13

¹¹ According to Glauser, 99% of e-cigarettes are manufactured in Shenzhen, China. *Pro. Decl.* Ex. F at 87:13-20.

¹² Master Distributors receive product directly from manufacturers in China. Pro. Decl. Ex. F at 74:17-21; 87:13-20.

¹³ E-cigarettes may be either disposable or reusable. Reusable e-cigarettes may have an "open system," meaning they have a reservoir that the user can refill with an e-liquid of the user's choice. Other types of reusables have "closed systems," meaning that they use an e-liquid contained in replaceable cartridges or pods that cannot be refilled. The distinction between the open and closed systems used in reusable e-cigarettes is analogous to the difference between a fountain pen and a ball-point pen. *See Liquid Labs LLC v. United States FDA*, 52 F.4th 533, 536 n.1 (3d Cir. 2022).

Magellan sells flavored e-cigarettes in the United States through trade channels that include wholesale e-cigarette distributors, such as Magellan's sister company Ecto World LLC, a/k/a Demand Vape. *Pro. Decl.* Ex. K ¶ 20. Magellan is the "purchasing arm" for Hyde products imported from China that are then transferred to Demand Vape. *Id.* Demand Vape and other wholesalers then distribute Hyde products to sub-distributors and independently-owned retail vape and convenience stores. *Id.* Magellan apparently also sells Hyde-branded e-cigarettes directly to retailers nationwide which in turn sell them to consumers at retail locations. *Pro. Decl.* Ex. J. ¶ 65. Until sales were halted by the FDA, Magellan sold Hyde and Juno products to more than 4,500 retailers nationwide. *Id.* Magellan or sister company Demand Vape distributes e-cigarette products "to retailers across New York." *Pro. Decl.* Ex. S.

The Hyde website, www.hydedisposables.com, advertises and sells flavored Hyde products exclusively, offering to enroll wholesalers as sellers of Hyde e-cigarettes. Among the benefits touted on the website are:

So Many Flavors!

Not only does Hyde boast an impressive range of flavored products, they are constantly growing it! From new fruit combinations, to menthol & tobacco collections; there's a Hyde perfect for your tastes.

Pro. Decl. Ex. C, www.hydedisposables.com.

On or about October 12, 2018, Magellan received a warning letter from the FDA stating FDA's belief that Magellan was manufacturing "new" tobacco products, including flavored eliquids, under the "Juno" name without the pre-market authorization required under the Tobacco Control Act. *Pro. Decl.* Ex. Q.¹⁴ Subsequent events showed this to be correct as Magellan only

¹⁴ All new tobacco products must have an FDA marketing authorization order in effect under section 910(c)(1)(A)(i) of the FD&C Act if otherwise exempt from the marketing authorization requirement. Without the statutorily required premarket authorization the products are marketed unlawfully and are subject to an FDA enforcement action. *Pro. Dec.* Ex. B at 16. All Hyde products are "new" tobacco products.

later applied for, on September 20, 2020, a pre-market authorization for Juno and Hyde products. *See Pro. Dec.* Ex. A at JA 11.

Although Magellan did file to obtain FDA pre-market authorization for several of its Hyde flavored e-cigarette products, including "Mango," "Pretzel Graham," and "Blue Razz," that premarket tobacco application ("PMTA") was denied by the FDA on or about October 6, 2022. See Magellan Tech., Inc. v. United States FDA, 70 F.4th 622, 622 (2d Cir. 2023). The FDA denied Magellan's PMTA because it found insufficient evidence to establish that marketing the products would be "appropriate for the protection of the public health." Id. That denial was recently affirmed by the Second Circuit Court of Appeals. Id. The marketing denial orders for 32 Hyde disposable, flavored e-cigarette products stated that the FDA had determined that Magellan's application lacked sufficient evidence to meet the "net benefit" standard required by the Tobacco Control Act, i.e., there was insufficient evidence to establish that flavored e-cigarettes provided smoking cessation benefits to adult smokers sufficient to outweigh the risk of youth e-cigarette initiation posed by flavors. Magellan Tech., 70 F.4th at 628-29:

[T]he FDA has determined that permitting the marketing of these products would not be appropriate for the protection of the public health. The company must stop selling and distributing these products, and those currently on the market must be removed or risk enforcement action.

Pro. Decl. Ex. A at JA 11.

Based on our review of your [PMTAs1, we determined that the new products, as described in your applications and specified in Appendix A, lack sufficient evidence to demonstrate that the marketing of these products is appropriate for the protection of the public health (APPH). Therefore, you cannot introduce or deliver for introduction these products into interstate commerce in the United States. Doing so is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA

Id. The FDA determined that

All of your PMTAs lack sufficient evidence demonstrating that your flavored ENDS will provide a benefit to adult users that would be adequate to outweigh the risks to youth. In light of the known risks to youth of marketing flavored ENDS, robust and reliable evidence is needed regarding the magnitude of the potential benefit to adult smokers.

Id.

By May 12 and 13, 2022, prior to the denial of Magellan's PMTA, Magellan had submitted additional PMTAs. On October 6, 2022, the FDA issued a "refusal to accept" order because of procedural deficiencies in the new applications. *See Vapor Train 2 LLC v. United States FDA*, No. 6:22-cv-00429, 2023 U.S. Dist. LEXIS 175979, at *8 (E.D. Tex. Sep. 29, 2023). The FDA's refuse-to-accept order provided that Magellan is barred from introducing into interstate commerce the ecigarette products covered in its applications. *Id.* at 12. Magellan sought a preliminary injunction directing the FDA to disregard its refuse-to-accept order and continue processing Magellan's PMTAs. *Id.* at *7. That motion was denied. *Id.* at *14-16. In sum, the FDA has affirmatively denied approval for the Juno and Hyde-brand flavored e-cigarettes imported by Magellan and distributed and sold by Demand Vape (and Empire Vape).

On May 31, 2023, the FDA issued warning letters to 30 retailers for illegally selling unauthorized tobacco products, including various Hyde disposable e-cigarettes. *Pro. Decl.* Ex. B. In an accompanying press release, the FDA noted:

Today, the U.S. Food and Drug Administration issued warning letters to 30 retailers, including one distributor, for illegally selling unauthorized tobacco products. The unauthorized products were various types of Puff and Hyde brand disposable e-cigarettes, which were two of the most commonly reported brands used by youth e-cigarette users in 2022.

Pro. Decl. Ex. B at 19. One such letter states:

[Y]ou offer for sale or distribution to customers in the United States the following [e-cigarette] products that lack a marketing authorization order: Hyde Rebel, Hyde

¹⁵ Magellan sought to make these supplemental filings in order to meet certain deadlines that would have stayed any enforcement actions by the FDA for selling unauthorized products until after its PMTA's had been decided.

Retro, and Hyde Edge. . . . These products do not have an FDA marketing authorization order in effect under section 910(c)(1)(A)(i) of the FD&C Act and are not otherwise exempt from the marketing authorization requirement. Therefore, these products are adulterated under section 902(6)(A) of the FD&C Act. In addition, these products are misbranded under section 903(a)(6) of the FD&C Act because a notice or other information respecting these products was not provided as required by section 905(j) of the FD&C Act.

Conclusion and Requested Actions

FDA has determined that your firm markets new tobacco products lacking premarket authorization in the United States. All new tobacco products on the market without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement action at FDA's discretion.

Pro. Dec. Ex. B at 16.

In terms of popularity, the 2022 National Youth Tobacco Survey reported that among current youthful users that had used a vape device at least once in the in the past 30 days and named a brand, Hyde was the sixth most popular brand, at 7.3 percent of users. Among current users, if the "use in past 30 days element" was dropped, Hyde products were the third most popular brand. ¹⁶

As described above, (*supra* at 5, 6) Magellan's Hyde products are common at smoke shops and convenience stores in New York City and have served as the predicate for numerous summonses issued by City enforcement agents to retail stores in each of the five boroughs for violations of Ad. Code § 17-715, the New York City flavor ban. *Hurst Decl.* ¶¶ 8, 9. Hyde flavored vapes were also observed at retail outlets in the City by PAVe and by Cross Border Solutions, which observed Hyde e-cigarettes in 15 stores. *Lesnak Decl.* Ex. A.

¹⁶ Cooper M, Park-Lee E, Ren C, Cornelius M, Jamal A, Cullen KA. *Notes from the Field: E-cigarette Use Among Middle and High School Students - United States*, 2022. MMWR Morb Mortal Wkly Rep. 2022 Oct 7;71(40):1283-1285. doi: 10.15585/mmwr.mm7140a3. PMID: 36201370; PMCID: PMC9541029.

Ecto World, LLC, d/b/a "Demand Vape"

Ecto World LLC d/b/a Demand Vape ("Demand Vape"), founded 2011, is a wholesaler of e-cigarettes and e-liquids co-founded and owned in part by Magellan owner Matthew Glauser, who is a Demand Vape partner and holds the titles of President and Chief Strategy Officer. *Pro. Decl.* Ex. F at 85:11-13; *Pro. Decl.* Ex. G ¶ 19. Demand Vape is located at the same address as Magellan. *Pro. Dec.* Ex. K ¶ 2. Glauser considers Demand Vape to be a "sister company" to Magellan; Magellan acts as Demand Vape's purchasing arm. *Pro. Decl.* Ex. H ¶ 17.

Demand Vape is one of the largest, if not the largest, e-cigarette distributors in the United States, offering approximately 30,000 products and selling to approximately 5,000 retailers in 49 states and internationally. *Pro. Decl.* Ex. F at 86:22-87:12; Ex. G ¶¶ 17-18, 20. As of December 2022, Demand Vape had 283 employees, 32 salespersons, *Pro. Decl.* Ex. F at 85:22-23, 91:13-15, annual revenue between \$500 and \$600 million and a monthly payroll in the millions. *Pro. Decl.* Ex. F at 87:21-23, 105:1-19; Ex. G at ¶ 18. Demand Vape distributes numerous brands of e-cigarettes in addition to the Hyde brand through the company sales team and a website, demandvape.com. *Pro. Decl.* Ex. E, Ex. F at 107:22-108:25.

Demand Vape is a master distributer of Hyde trademarked e-cigarettes, which it distributes "throughout the entire country and some internationally." *Pro. Decl.* Ex. F at 87:16-23. Demand Vape sells Hyde products despite the absence of pre-market authorization from FDA for those products even in the face of the October 12, 2018, FDA warning letter to "sister company" Magellan stating that unauthorized e-cigarettes were illegal under the Tobacco Control Act and

exposed sellers to enforcement actions if marketed without authorization. *See Pro. Decl.* Ex. A at JA 11, Ex. B.¹⁷

Demand Vape's website, demandvape.com, has displayed an extensive selection of Hyde products, *Pro. Decl.* Ex. E, Ex. F at 107:22-108:25, which are sold from the website in master case quantities of 200 or 300 devices and display case quantities of 70 devices. *Pro. Decl.* Ex. E. Hyde products were Demand Vape's largest seller in 2021, but have since been eclipsed by another illegal disposable flavored e-cigarette, "Elf Bar." *Pro. Decl.* Ex. F at 107:4-8. Elf Bar is the number 1 selling e-cigarette brand in the U.S., so popular that its sales exceed the two principal FDA-approved, legal e-cigarette brands, R.J. Reynolds' Vuse and Altria's Juul. *Pro. Decl.* Ex. F at 88:18-89:3.

Demand Vape is also a master distributor of Elf Bar e-cigarettes, a disposable flavored e-cigarette that is also unapproved and hence illegal for sale in the United States, but which Demand Vape sells in enormous, highly profitable quantities. *Pro. Decl.* Ex. I ¶ 5, Ex. Q. Elf Bar sales account for anywhere from 25 to 35 percent of Demand Vape's revenues, and about one-third of Demand Vape's overall profits because it is not only one of the most popular products, it also has one of the highest profit margins of any disposable e-cigarette. *Pro. Decl.* Ex. F, at 89:4-8; 105:23-25; Ex. G, ¶ 73. For Demand Vape, Elf Bar's profit margin of 30% is approximately double that of the average profit of 15% across all of Demand Vape's products. *Pro. Decl.* Ex. F at 119:10-18. Thus, from October 2021 to October 2022, Demand Vape's Elf Bar revenue alone exceeded

¹⁷ Demand Vape nonetheless recognizes that "Warning Letters are an enforcement activity and a common way for FDA to signal that there is an issue with a company's conduct or product, and that the product appears to be an unauthorized new tobacco product." *Pro. Decl.* Ex. G 38.

¹⁸ In March 2023, Elf Bar's manufacturer was enjoined under the Lanham Act from selling e-cigarettes under the name "Elf Bar" in the United States. Prior to that injunction, as of February 2023, Elf Bar accounted for 40% of Demand Vape's total revenue, and a substantial portion of Demand Vape's profits. *Pro. Decl.* Ex. I, ¶ 5.

\$132,060,066 for a gross profit of \$38,271,264.24. *Pro. Decl.* Ex. Q. Demand Vape's sales of Elf Bar-branded products have continued to increase over the last year, resulting in over \$38 million in profits for Demand Vape. *Pro. Decl.* Ex. G ¶ 72.

On June 22, 2023, the FDA announced it issued warning letters to 189 retailers for illegally selling unauthorized products, specifically Elf Bar products that appeal to youth.¹⁹

No flavored e-cigarettes or flavored e-liquids sold by Demand Vape, including Hyde brand e-cigarettes, have been granted pre-market authorization by the FDA. *Pro. Decl.* Ex. B; *see https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-two-vuse-solo-menthol-e-cigarette-products* (the only e-cigarette devices that may be lawfully sold in the United States are tobacco-flavored).²⁰

Demand Vape also sells numerous other brands of flavored e-cigarettes and flavored e-liquids to sub-distributors, and also sells those products directly to retail vape shops, smoke shops and convenience stores. For example, Demand Vape invoices in the total amount of \$214,905 show that Demand Vape sold flavored e-cigarettes to Star Vape in Brooklyn, including Hyde brand and Elf Bar, between November 2020 and April 2023. *Pro. Decl.* Ex. S.

Mahant 56 LLC, d/b/a Empire Vape

Mahant Krupa 56 LLC, d/b/a Empire Vape Distributors, is a "Wholesaler & Distributor of Tobacco & Tobacco Products," located at 56-01 Maspeth Avenue, Maspeth, New York, owned and controlled at least in part by defendants Nikunj Patel and Devang Koya (collectively, "Empire

¹⁹ See https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products#3.

²⁰ The list of FDA approved e-cigarettes is available at https://www.fda.gov/tobacco-products/premarket-tobacco-products, no Hyde products and no Elf Bar products have been approved. The list of approved e-cigarettes is also available at https://digitalmedia.hhs.gov/tobacco/print materials/CTP-250?locale=en and contains no flavored e-cigarettes.

Vape"). Empire Vape distributes e-cigarettes and e-liquids at wholesale to smoke and vape shops and convenience/grocery stores. *See* http://Empiresmokedist.com.

Empire Vape maintains a website offering a wide variety of e-cigarettes, at http://Empiresmokedist.com. The website's banner previously stated "FLAVOR BAN? NO WORRIES. WE GOT YOU." (last visited June 19, 2023). Following filing of this action, that banner appears to have been removed. Empire Vape's website offered as of June 19, 2023, Magellan-trademarked Hyde e-cigarettes in many flavors, including Banana Ice, Lush Ice, Blueberry and Cola 10 packs of 5% nicotine Hyde Edge Recharge 3300 puff, and 5% nicotine 10 packs of Banana Cream, Brazmallows and Energize flavors Hyde N-Bar Disposable 4500 puff. *Pro. Decl.* Ex. N.

On March 23, 2021, the Office of the New York City Sheriff conducted an administrative inspection of Empire Vape at its 56-01 Maspeth Avenue, Maspeth, New York warehouse. The inspection revealed thousands of units of flavored e-cigarette and e-liquids. *Pro. Decl.* Ex. N. Included among the e-cigarettes discovered by the Office of the Sheriff were cases of Hyde e-cigarettes containing 320 units each, all with the designation "Made in China," including Hyde Plus Disposable Strawberry & Cream, Neon Rain, Pina Colada, Blue Razz Ice, Pineapple Peach Mango, Pink Lemonade and Pineapple Ice. *Id.* The Sheriff also identified Hyde products that had been removed from cases, displayed as "10 packs," in such flavors as Sour Apple Ice, Aloe Grape,

Raspberry Watermelon, Lush Ice, Banana Ice, Peach Mango Watermelon, and Strawberry Banana



Pro Decl. Ex. N — Cartons of Hyde Flavored Vapes At Empire Vape Warehouse



Pro. Decl. Ex. N— Hyde Blue Razz Ice, Aloe Grape & Sour Apple Ice at Empire Vape

The Sheriff also identified invoices documenting sales of flavored e-cigarette to retail convenience stores in New York City and elsewhere. *Pro. Decl.* Ex. O.

ARGUMENT

POINT I.

THE COURT SHOULD ENJOIN DEFENDANTS' TRANSACTIONS WITH FLAVORED E-CIGARETTES IN AND INTO NEW YORK CITY

Flavored e-cigarettes that should be rare in New York City because of the City's flavor ban are instead ubiquitous as a result of Defendants' conduct. Magellan and Demand Vape owner Jon Glauser admits to the companies' distribution of flavored e-cigarette to "retailers across New York," and in fact has sold many thousands of Hyde, Elf Bar and other brands of e-cigarettes to Star Vape in Brooklyn. *Pro. Decl.* Ex. S. Empire Vape distributes those and other brands of e-cigarettes throughout the City. Flavored e-cigarettes are highly attractive to youth and are sold on an increasing basis to persons below the age of 21 by retailers in the City. Approximately 65% of City stores visited by Cross Border (*Lesnak Decl.* ¶ 6), and 60% by PAVe (*Berkman Decl.* ¶ 7) sell flavored e-cigarettes, often containing nicotine at far higher levels than conventional cigarettes (*Morse Decl.* ¶ 6) and classed as "adulterated" under the Food Drug & Cosmetics ("FD&C") Act. *Pro. Decl.* Ex. B at 16.²¹ Approximately 93% of the stores from which PAVe volunteers made purchases were not licensed to deal in e-cigarettes. *Berkman Decl.* ¶ 8.

The City accordingly seeks to (1) preliminarily enjoin Magellan and Demand Vape – who are located outside of New York City – from continuing to sell or offering to sell flavored ecigarettes or flavored e-liquids to any person located in New York City, and (2) preliminarily enjoin Empire Vape – located within New York City – from continuing to sell, offering to sell,

²¹ Products that do not have an FDA marketing authorization order in effect under section 910(c)(1)(A)(i) of the Food Drug & Cosmetics ("FD&C") Act and are not otherwise exempt from the marketing authorization requirement are "adulterated" under section 902(6)(A) of the FD&C Act. *Pro. Decl.* Ex. B at 16.

possessing with intent to sell and possessing with intent to offer for sale flavored e-cigarettes and e-liquids. *See, e.g., N.Y. Trap Rock Corp. v. Clarkstown*, 299 N.Y. 77 (1949).²²

A preliminary injunction generally requires showing (1) a likelihood of success on the merits; (2) irreparable harm; (3) a balance of the equities tipped in the movant's favor and (4) a public interest served by issuance of a preliminary injunction. *Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008); *City of N.Y. v. Golden Feather Smoke Shop, Inc.*, 597 F.3d 115, 120 (2d Cir. 2010).

A. The City Need Not Show Irreparable Harm

When a statute authorizes injunctive relief to remedy a violation, government plaintiffs need not plead or prove irreparable harm: an injunction will issue upon a showing of probable cause to believe that the statute is being violated. *California v. Am. Stores Co.*, 495 U.S. 271, 295 (1990) ("In a Government case the proof of the violation of law may itself establish sufficient public injury to warrant relief."); *Golden Feather*, 597 F.3d at 121 ("the City was not required to make a showing of irreparable harm to obtain an injunction under ... statutes [that] authorize injunctive relief for violations."). In making specific conduct unlawful by statute, the legislature has determined "that such conduct, in and of itself, is harmful to the public." *Golden Feather*, 597 F.3d at 121, *affirming City of New York v. Golden Feather Smoke Shop, Inc.*, 2009 U.S. Dist. LEXIS 76306, at *112 (E.D.N.Y. Aug. 25, 2009) ("[A] statute's enactment constitutes Congress' implied finding that violations will harm the public") (quoting *United States v. Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d 30, 49-50 (E.D.N.Y. 2001) (internal quotation marks and citations omitted)). New York law likewise does not require government actors to demonstrate irreparable harm. *City of N.Y. v. Beam Bike Corp.*, 206 A.D.3d 44 (1st Dep't 2022) ("A

²² The City limits the scope of the injunctive relief sought by this motion to a restraint on Defendants' violation of Ad. Code § 17-715 (b) and/or Defendants creation and maintenance of a public nuisance. The City reserves its right to move to enjoin violations of the PACT Act, 15 U.S.C. § 375 *et seq.*, N.Y. Public Health Law § 1399-*ll* ("PHL §1399-*ll*"), and N.Y. Public Health Law § 1399-mm-(1) ("PHL §1399-mm-(1)") following appropriate discovery.

municipality seeking a preliminary injunction to enforce compliance with its ordinances or regulations in order to protect the public interest . . . need only demonstrate a likelihood of success on the merits and that the equities weigh in its favor; it is not required to show proof of irreparable harm.").

Even absent that presumption, the facts marshalled above establish that the Defendants cause or contribute to a threat to public health that is quintessentially irreparable harm. "Monetary damages and penalties are inadequate remedies given the public health risks associated with cigarettes, and, the public interest would in fact benefit and not be disserved by the granting of a permanent injunction." *City of N.Y. v. Nappi*, 2021 U.S. Dist. LEXIS 238140, at *16 (S.D.N.Y. Dec. 10, 2021), *decision adopted City of N.Y. v. Dennis*, 2022 U.S. Dist. LEXIS 689 (S.D.N.Y. Jan. 3, 2022).

B. The City Is Likely To Succeed On The Merits Of Its Claim That Defendants Violate Ad. Code § 17-715 (b)

The "likelihood of success on the merits" necessary for the issuance of a preliminary injunction requires only that the City establish the occurrence of the Defendants' violations "more likely than not." *See Eng v. Smith*, 849 F.2d 80, 82 (2d Cir. 1988).²³ The City shows below

²³ The Second Circuit will at times substitute for "success on the merits" a showing of "serious questions on the merits and a balance of hardships equities decidedly favoring the moving party." *City of N.Y. v. Golden Feather Smoke Shop, Inc.*, 597 F.3d 115, 121 (2d Cir. 2010). However, that test is intended to apply only when a district court "cannot determine with certainty that the moving party is more likely than not to prevail on the merits of the underlying claims." *Citigroup Glob. Mkts., Inc. v. VCG Special Opportunities Master Fund, Ltd.*, 598 F.3d 30, 35 (2d Cir. 2010) (citing *F. & M. Schaefer Corp. v. C. Schmidt & Sons, Inc.*, 597 F.2d 814, 815-19 (2d Cir. 1979)). As shown here, that is not so in this case where success on the merits can be shown with the requisite certainty of more probably than not.

The more stringent "substantial likelihood of success" standard applies only if injunctive relief would provide substantially all the relief sought in the complaint. *Lichtenberg v. Besicorp Grp. Inc.*, 43 F. Supp. 2d 376, 384 (S.D.N.Y. 1999). That again is not the case here where in addition to an injunction the City's complaint seeks monetary damages and nuisance abatement.

that Defendants have indeed "more likely than not" violated NYC Administrative Code § 17-715 (b) 1 and/or created a public nuisance.

New York City prohibits the sale, offering for sale, possessing with intent to sell or possessing with intent to offer flavored e-liquids and e-cigarettes:

Sale of flavored tobacco products, flavored electronic cigarettes and flavored e-liquid prohibited:

* * *

- **b**. 1. It shall be unlawful for any person to sell or offer for sale, or to possess with intent to sell or offer for sale, any flavored electronic cigarette or flavored e-liquid.
- 2. There shall be a presumption that an electronic cigarette retail dealer, as defined in section 20-560, in possession of six or more flavored electronic cigarettes, or more than 12 fluid ounces (354.882 mL) of flavored e-liquid, possesses such flavored electronic cigarettes or flavored e-liquid with intent to sell or offer for sale.

NYC Administrative Code 17-715 (b).²⁴ Even without considering the hundreds of Hyde ecigarettes in City stores (for which Magellan and Demand Vape are master distributors), Demand

Characterizing flavor. The term "characterizing flavor" means a distinguishable taste or aroma, other than the taste or aroma of tobacco, imparted either prior to or during consumption of a tobacco product, electronic cigarette or e-liquid, including, but not limited to, tastes or aromas relating to any menthol, mint, wintergreen, fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, herb, spice, or any "concept flavor" that imparts a taste or aroma that is distinguishable from tobacco flavor but may not relate to any particular known flavor; provided, however, that no tobacco product, electronic cigarette or e-liquid shall be determined to have a characterizing flavor solely because of the use of additives or flavorings or the provision of ingredient information.

Electronic cigarette. The term "electronic cigarette" has the same meaning as such term is defined in section 20-560.

E-liquid. The term "e-liquid" has the same meaning as such term is defined in section 20-560.

Flavored electronic cigarette. The term "flavored electronic cigarette" means any electronic cigarette that imparts a characterizing flavor. A public statement or claim made or disseminated by the manufacturer of an electronic cigarette, or by any person authorized or permitted by the

²⁴ The definitions applicable to Ad. Code 17-715 are set forth in Ad. Code 17-713:

Vape sold \$200,000-worth of e-cigarettes, at wholesale prices, to Star Vape in Brooklyn, *Pro. Dec.* Ex. S. That is a facial violation of the statute. Discovery will undoubtedly reveal still more sales into the City by this "largest, if not the largest, e-cigarette distributor[] in the United States," *Pro. Decl.* Ex. F at 86:22-87:12; Ex. G at ¶¶ 17-18, 20, whose business is to "ensure that retailers across New York" are able to offer flavored e-cigarettes to their customers. *Pro. Dec.* Ex. R; *see also* Ex. N (Magellan's Hyde products at Empire Vape); *Berkman Decl.* Ex. A (Magellan's Hyde products at New York City stores); *Lesnak Decl.* (Magellan's Hyde products at New York City and State stores).

The Second Circuit upheld an earlier version of this statute that prohibited the sale of flavored tobacco products, rejecting a preemption challenge under the Tobacco Control Act, holding that Ad. Code § 17-715 was an "exercise [of the City's] police powers to protect the health and safety of its citizens," *id.* at 432, and actually served to advance the Tobacco Control Act's "objective of reducing the use and harmfulness of tobacco products, especially among young people." *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of N.Y.*, 708 F.3d 428, 432, 436 (2d Cir. 2013); *accord Eastchester Tobacco & Vape Inc. v. Town of Eastchester*, 618 F. Supp. 3d 155 (S.D.N.Y. 2022); *Indeps. Gas & Serv. Stations Ass'ns v. City of Chi*cago, 112 F. Supp. 3d 749, 753 (N.D. Ill. 2015) (referring to "Congress's explicit decision to preserve for the states a robust

manufacturer to make or disseminate public statements concerning such electronic cigarette, that such electronic cigarette has or produces a characterizing flavor shall constitute presumptive evidence that such electronic cigarette is a flavored electronic cigarette.

Flavored e-liquid. The term "flavored e-liquid" means any e-liquid that imparts a characterizing flavor. A public statement or claim made or disseminated by the manufacturer of an e-liquid, or by any person authorized or permitted by the manufacturer to make or disseminate public statements concerning such e-liquid, that such e-liquid has or produces a characterizing flavor shall constitute presumptive evidence that such e-liquid is a flavored e-liquid.

role in regulating, and even banning, sales of tobacco product") (quoting *U.S. Smokeless Tobacco*, 708 F.3d at 436); see also R.J. Reynolds Tobacco Co. v. City of Edina, 60 F.4th 1170 (8th Cir. 2021) ("State governments historically possess police power to protect public health and safety.").²⁵

The City's enactment of several laws regulating e-cigarettes, including the ban of flavored e-cigarettes and e-liquids, and the age restrictions thereon, bespeaks the City's strong interest in enforcing its policies. *Powers-Barnhard v. Butler*, 2020 U.S. Dist. LEXIS 151997, at *33 (N.D.N.Y. Aug. 21, 2020) (enactment of regulatory legislation is evidence of "a special public policy interest in the subject matter of [a] litigation.") (quoting *City of New York v. A-1 Jewelry & Pawn, Inc.*, 247 F.R.D. 296, 342 (E.D.N.Y. 2007) ("By enacting strong gun control laws to protect its citizens from gun-related crimes New York has expressed a special public policy interest in the subject matter of this litigation.").

As described at length above, there is abundant, incontrovertible evidence that each Defendant sells or offers for sale, or possesses with intent to sell or offer for sale, flavored electronic cigarettes and flavored e-liquids:

Magellan	Demand Vape	Empire Vape
Magellan's Hyde products	Demand Vape invoices	Sheriff's inspection in
are ubiquitous in the City.	show \$200,000 in sales	March 2012 shows
Berkman Decl. Ex. A.	of flavored e-cigarettes	abundant e-cigarette
Lesnak Decl. Ex. A.	to Star Vape in	inventory, including
	Brooklyn. Pro. Decl.	Hyde e-cigarettes, some
	Ex. S.	direct from China. Pro.
		Decl. Ex. N

²⁵ The use of state and local police powers to ban sales of tobacco products "for the preservation of the public health or safety" is long-standing. *See Austin v. Tennessee*, 179 U.S. 343, 349 (1900) ("[W]e should be shutting our eyes to what is constantly passing before them were we to affect an ignorance of the fact that a belief in [tobacco's] deleterious effects, particularly upon young people, has become very general, and that communications are constantly finding their way into the public press denouncing their use as fraught with great danger to the youth of both sexes.").

Magellan's website	Demand Vape's	Sheriff's inspection in
Hydedisposables.com	website displays e-	March 2012 locates
displays Hyde products	cigarettes for sale with	invoices of sales to
with no restriction on sales	no restriction on sales	stores in the City. Pro.
to New York City. Pro	to New York City. Pro	Decl. Ex. O
Decl. Ex. C.	Decl. Ex. E.	
Magellan ensures the	Demand Vape ensures	Empire Vape's website
availability of e-cigarettes	the availability of e-	displays e-cigarettes for
to retailers across New	cigarettes to retailers	sale with no restriction
York. Pro Dec. Exs. R, S	across New York. Pro	on sales to New York
	Dec. Exs. R, S	City. Pro Decl. Ex. N.

Accordingly, Magellan, Denad Vape, Empire Vape and their principals should be enjoined from continuing to violate NYC Administrative Code 17-713.

C. The City Is Likely To Succeed On The Merits Of Its Claim That Defendants Create, Contribute To and Maintain A Public Nuisance

The City is also likely to succeed on its claim that Defendants cause, contribute to and maintain a public nuisance. A public nuisance "is an offense against the State" that "consists of conduct or omissions which offend, interfere with or cause damage to the public in the exercise of rights common to all, in a manner such as to . . . endanger or injure the property, health, safety or comfort of a considerable number of persons." *Janki Bai Sahu v. Union Carbide Corp.*, 528 F. App'x 96, 101 (2d Cir. 2013) (quoting *Copart Indus. v. Consol. Edison Co. of New York*, 41 N.Y.2d 564, 568, (1977)); *see also Reid v. Kawasaki Motors Corp.*, 189 A.D.2d 954, 957 (3d Dep't 1993) ("The *sine qua non* of an action for public nuisance ... is the interference by a defendant with a public right."). A plaintiff asserting a public nuisance claim must prove: "1) the existence of a public nuisance; [and] (2) conduct or omissions by a defendant that create, contribute to, or maintain the public nuisance." *City of New York v. Artisan Vapor Franchise LLC*, 2020 U.S. Dist. LEXIS 205315, *5 (S.D.N.Y. Nov. 2, 2020) (enjoining out-of-City e-cigarette sellers from selling into the City). In certain circumstances, a plaintiff must also show "factual causation,"

which requires "proof that a defendant, alone or with others, created, contributed to, or maintained the alleged interference with the public right." *City of New York v. Milhelm Attea & Bros., Inc.*, 550 F. Supp. 2d 332, 351 (E.D.N.Y. 2008). In the fact section above the City has demonstrated all of the elements constituting a public nuisance, warranting a preliminary injunction.

1. The City Has Demonstrated Injury to the Health of its Citizens

There is no doubt that the distribution and sale of e-cigarettes and e-liquids in violation of federal, state, and local law is a public nuisance because it "involves a significant interference with the public health," which is "a right common to the general public." *In re Juul Labs, Inc., Mktg., Sales Practices, & Prods. Liab. Litig.*, 497 F. Supp. 3d 552, 647 (N.D. Cal. 2020) (quoting *Restatement (Second) of Torts*§ 821B) (applying New York law); *In re Opioid Litigation*, 2018 N.Y. Misc. LEXIS 2428 (Sup. Ct. Suffolk Co. 2018) (defendants failed to establish that public health is not a right common to the general public). Indeed, the New York Court of Appeals holds that a municipal corporation may "bring an action to restrain a public nuisance which allegedly has injured the health of its citizens." *New York Trap Rock Corp. v. Town of Clarkstown*, 299 N.Y. 77, 83-84 (1949). "[I]t is clear that a public nuisance which injures the health of the citizens of a municipality imperils the very existence of that municipality as a governmental unit." *Id.* "Where the public health is a factor, a municipality's right to bring 'an action [for an injunction] may be tantamount to its right of survival." *City of New York v. Beretta U.S.A. Corp.*, 315 F. Supp. 2d 256, 273-74 (E.D.N.Y. 2004) (quoting *Clarkstown*, 299 N.Y. 83-84).

The City has shown above that there is injury to the public health of its citizens through the proliferation of e-cigarettes and e-liquids because those products incontrovertibly endanger the health of the City's youth. *See Morse Decl.* ¶¶ 5, 8, 9 (describing the health impacts of e-cigarette use); *see generally Daniels Decl.*, *Hodgkin's Decl.*, *Marais Decl.* Courts have already held that

"youth e-cigarette use and wholesale addiction of kids to nicotine" constitutes "a public health crisis," permitting municipalities to bring public nuisance claims. *Juul Labs*, 497 F. Supp. 3d at 648; *see also City of N.Y. v. Artisan Vapor Franchise LLC*, 2020 U.S. Dist. LEXIS 205315, at *6-7 (E.D.N.Y. Nov. 2, 2020) (holding that "underage e-cigarette use" is an endangerment to "the health of New York City youth" and granting the City's request for injunctive relief against a seller of e-cigarettes). Courts have also found that the presence of statutes targeting e-cigarettes underscores the extent of the injury to public health. *See Artisan Vapor*, 2020 U.S. Dist. LEXIS 205315, at *5 ("[T]he fact that the City passed Administrative Code § 17-706, prohibiting the sale of e-cigarettes to people under the age of twenty-one further supports the allegation that a public nuisance exists.").

Accordingly, the City has demonstrated that it has – and is – suffering an injury to the public health of its residents through the flood of e-cigarettes and e-liquids into the marketplace that is fueled by these Defendants.

2. The City Has Shown that Defendants Engaged in Unlawful Conduct

Nuisance is a unique form of tort liability requiring neither a duty to another nor conduct that is *per se* tortious. *New York v. Shore Realty Corp.*, 759 F.2d 1032, 1051 (2d Cir. 1985) (defendant liable for public nuisance irrespective of negligence or fault). Liability for the harm caused to third parties instead generally turns on (a) whether the defendant's actions were intentional and (b) unreasonably interfered with a public right yielding actual (or imminent) injury. *Restatement (Second) of Torts* §§ 821B (1), *cmt.* e, 822, *cmt.* A. In this case, however, the City does not even need to demonstrate that Defendants' conduct is intentional or unreasonable – it is, and the City has – because their conduct violates a statutory prohibition, qualifying as a "nuisance *per se.*"

To establish a nuisance *per se*, a plaintiff need show only a violation of law; no proof of intent, negligence or even unreasonableness is necessary:

The City's reliance on two New York State statutes . . . serves as evidence of a nuisance *per se*. "When the conditions giving rise to a nuisance are also a violation of statutory prohibition, those conditions constitute a nuisance *per se*, and the issue of the reasonableness of the defendant's conduct and the weighing of the relative interests of the plaintiff and defendant is precluded because the Legislature has, in effect, already struck the balance in favor of the innocent party.

City of N.Y. v. A-1 Jewelry & Pawn, Inc., 247 F.R.D. 296, 355 (E.D.N.Y. 2007) (quoting Branch v. W. Petro., Inc., 657 P.2d 267 (Utah 1982)). Here, the City has shown that Defendants' sales and deliveries into New York City violate at least Ad. Code § 17-715. Accordingly, the City need not prove that Defendants' conduct was intentional and unreasonable.²⁶

3. The City Has Demonstrated Causation

"Satisfaction of the causation requirement for liability in a public nuisance action requires specifically proof that a defendant, alone or with others, created, contributed to, or maintained the alleged interference with the public right." *NAACP v. AcuSport, Inc.*, 271 F. Supp. 2d 435, 492 (E.D.N.Y. 2003); *see also Penn Ctr. Transp. Co. v. Singer Warehouse & Trucking Corp.*, 86 A.D.2d 826 (1st Dep't 1982) ("Everyone who creates a nuisance or participates in the creation or

Id. at 10 (citations and parentheticals omitted).

²⁶ Defendant Demand Vape has argued on grounds analogous to nuisance *per se* that e-cigarette manufacturers like its sister company Magellan that market unapproved e-cigarettes should be stripped of their trademark rights. *See VPR Brands, LP v. Shenzhen Weiboli Technology, Co.*, Ltd., *et al*, No. 9:22-cv-81576 (S.D. Fla.), Doc. # 80 at 10 (citing *Dessert Beauty, Inc. v. Fox*, 617 F. Supp. 2d 185, 190 (S.D.N.Y. 2007) (observing that "a party that is in violation of the Food, Drug and Cosmetic Act . . . for not complying with federal labeling regulations cannot obtain a federally registered trademark, nor can it maintain or enforce a previously obtained trademark"). Demand Vape asserts:

A per se violation of a statute regulating the sale of a party's goods constitutes sufficient grounds for finding unlawful use. Here, 21 U.S.C. § 387j(a) requires an FDA marketing authorization order for any tobacco product, including electronic cigarettes, introduced into U.S. commerce after February 15, 2007. Any product lacking such a marketing authorization order is "adulterated." 21 U.S.C. § 387b(6)(A).

maintenance thereof is liable for it."). ²⁷ In addition, some courts inquire into whether a defendant's act or omission was a "substantial factor" in bringing about the injury. *In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig.*, 725 F.3d 65, 116 (2d Cir. 2013) (applying New York law). The City has shown that each Defendant participated in the creation and maintenance of the public nuisance and that their conduct was a "substantial factor" in bringing about the injury.

Under New York's flexible "substantial participation" standard, an upstream manufacturer introducing a toxic substance into the stream of commerce is liable for public nuisance in the face of evidence that the manufacturer, having sold a toxic or dangerous substance to an identified third party, continued to sell the product to that party knowing that the nuisance will continue by the third-party's continued use. *Suez Water N.Y. Inc. v. E.I. du Pont de Nemours & Co.*, 2023 U.S. Dist. LEXIS 48925, at *17-21 (S.D.N.Y. Mar. 22, 2023)("Suez Water"). ²⁸ "Substantial participation" in a nuisance is invariably established where the "defendant... had knowledge that its product would be used in a manner that would create a nuisance, [and] also sold the product directly and continuously to the person engaged in the nuisance-creating activity even after acquiring the knowledge that that person was creating a nuisance." *Id.* at *49. Defendants Magellan and Demand Vape have acquired that precise knowledge but respond in a manner fully

²⁷ Accord Hine v. Aird-Don Co., 232 A.D. 359 (3d Dep't 1931); McNulty v. Ludwig & Co., 153 A.D. 206, (2d Dep't 1912) (once a public nuisance is established "all who participated in creating or maintaining such nuisance were jointly and severally liable for it"); Uggla v. Brokaw, 117 A.D. 586 (1st Dep't 1907) (same).

²⁸ There is nothing far-fetched in labeling e-cigarettes as incorporating toxic or dangerous substances. The Environmental Protection Agency has done just that:

Nicotine is a commercial chemical product listed in 40 CFR 261.33(e) and is an acute hazardous waste (EPA waste code P075) when disposed. EPA has concluded that nicotine is the sole active ingredient of the e-liquid in e-cigarettes and thus a commercial chemical product, e-cigarettes are not manufactured articles, and e-cigarette cartridges are considered containers of nicotine. Therefore, e-cigarettes may be regulated as acute hazardous waste P075 when disposed.

consistent with a conclusion that they intend to continue selling their product to City retailers.. *See infra* at "D."

The present facts establish that each Defendant substantially participated in the creation of the public nuisance. Magellan 1) is the principal importer into the United States of flavored, nicotine-containing Hyde e-cigarettes identified as present in City retail stores²⁹; 2) the Hyde e-cigarettes – and dozens of other brands – were supplied by Demand Vape directly or through sub-distributors to those City retail stores; 3) Magellan and Demand Vape know that retail stores in the City sell e-cigarettes to the public, that in fact is the sole purpose of their supplying e-cigarettes to retail stores; and 4) Magellan and Demand Vape know that young people have been avid customers for Hyde products and disposable e-cigarettes generally. They were accordingly "substantially certain" that "there would be a tendency" for flavored e-cigarette use "to spread quickly" to young people once those e-cigarettes were offered publicly at retail. 30 See Suez Water, at *17-21.

In determining whether a defendant's conduct constitutes a substantial factor, consideration is given to (1) the number of contributing factors for which the defendant was not responsible; (2) whether the defendant contributed continuously, up to the time of harm, and (3) the lapse of time since the defendant's contribution. *In re MTBE Prod. Liab. Litig.*, 739 F. Supp. 2d 576, 596 (S.D.N.Y. 2010). Foreseeability of harm is also a consideration when analyzing whether a defendant's actions are a substantial factor in the plaintiff's injuries. *Suez Water*, 2023

²⁹ To the extent Magellan did not itself manufacture flavored e-cigarettes, owner Jon Glauser testified that Magellan formed a relationship with a Chinese manufacturer in Shenzhen, China (where 99% of e-cigarettes are manufactured) *Pro. Decl.* Ex. F at 87:13-20. Magellan purchases e-cigarette products from the manufacturer under contracts in which Magellan serves as the Hyde master distributor for the Hyde products, and for which Magellan owns the trademarks. *Id.* Magellan also purchases e-cigarette products for distribution by its sister company, Demand Vape. *Pro. Decl.* Ex. H.

³⁰ Magellan's owner, Jon Glauser, has stated that he understands critics' concerns that sweet-flavored e-cigarettes will appeal to teens, potentially addicting them. He accordingly knows that youths purchase Hyde e-cigarettes. *Pro. Decl.* Ex. C.

U.S. Dist. LEXIS 48925, at *47) (citing *Hain v. Jamison*, 28 N.Y.3d 524 (2016) (whether an act is a "substantial cause of the plaintiff's injuries . . . turns upon questions of foreseeability").

It is virtually self-evident that each Defendant's conduct – through the importation, distribution, and sale of flavored e-cigarettes – qualifies as a substantial factor in unreasonably interfering with the public health. (i) Although other e-cigarette distributors contribute to the nuisance, the facts show that Magellan's and Demand Vape's participation is far from de minimis, where Elf Bar and Hyde e-cigarettes have both been highly popular; see Pro. Decl. Ex. F at 88:18-89:3 (Elf Bar is the number 1 seller), supra at 13 (Hyde's high popularity); (ii) the facts above show Defendants' contribution to the nuisance as having been continuous (see, e.g., Pro. Decl. Ex. S (sales into the City over at least 3 years); and (iii) Defendants' conduct is current and ongoing. See Berkman Decl.; Lesnak Decl. (present store presence). Each Defendant has contributed to the proliferation of flavored e-cigarettes in New York City. Magellan imports flavored e-cigarettes into the country from China, Demand Vape distributes them nationally, including to New York City, and Empire Vape distributes the products to retail stores in the City, from where they are sold to the public. The sole reason that retail stores in New York City have a steady supply of flavored e-cigarettes is because Defendants form a supply chain that imports and distributes those products to those stores. By supplying retailers with e-cigarettes it is certainly foreseeable that there will be sales to persons below the age of 21. See n. 30.

D. Defendants Are Likely To Continue Their Violations

Issuing an injunction requires proof of "a reasonable likelihood that the wrong will be repeated." *SEC v. Manor Nursing Centers, Inc.*, 458 F.2d 1082, 1100 (2d Cir. 1972); *Blue Ribbon Smoked Fish*, 179 F. Supp.2d at 50 ("To enjoin future behavior, the government must show that

defendants have violated the [statute] and that there is some reasonable likelihood that the violations may recur.").

It is more than "reasonably likely" that Defendants will continue to distribute flavored ecigarettes in and into the City. To begin with, "the commission of past illegal conduct is highly suggestive of the likelihood of future violations." SEC v. Mgmt. Dynamics, Inc., 515 F.2d 801, 807 (2d Cir. 1975). More significantly, Defendants' product lines consist in large measure of flavored vapes. Pro. Decl. Exs. C, E, N. The revenue and profits Defendants earn from the products is enormous, Pro. Decl. Ex. Q, and are not likely to be surrendered lightly. Indeed, at least Magellan and Demand Vapes' response to the present action makes it reasonably conclusive that they will continue their conduct: When served with the complaint, defendants Magellan, Demand Vape, Glauser and Hashagen denied any wrong-doing, claimed compliance with all applicable laws – an obvious falsehood in the face of i) sales of adulterated products (*Pro. Decl.* Exs. A, B, P); ii) into New York City (Pro. Decl. Ex. S) – and threatened retaliation against the City's attorneys.³¹ Defiance of that nature is far from suggestive of an intent to discontinue the conduct through which they are maintaining a public nuisance. See Commodity Futures Trading Com. v. British Am. Commodity Options Corp., 560 F.2d 135, 142 (2d Cir. 1977) (clear likelihood of future violations where company maintained its activities were legitimate and persisted in those activities until the day of court hearing).

Magellan, Demand Vape, Glauser and Hashagen characterized the present action as a "baseless attack," threatening to seek sanctions against the City attorneys signing the complaint. These defendants contended to have "scrupulously complied with all relevant federal, state, and city requirements in the operation of their business. https://vaping360.com/vape-news/125167/new-york-city-lawsuit-accuses-vape-distributors-of-racketeering/, a claim false on its face given, *inter alia*, Demand Vape's later admission of deliveries of flavored e-cigarettes to retailers "across New York" (*Pro Decl.* Ex. R), where flavored e-cigarettes are flatly illegal. *See N.Y. Pub. Health Law* § 1399-mm-1 ("No vapor products dealer, or any agent or employee of a vapor products dealer, shall sell or offer for sale at retail in the state any flavored vapor product intended or reasonably expected to be used with or for the consumption of nicotine."). Glauser's subsequent screed (*Pro. Decl.* Ex. R) made an assertion that the action is "politically motivated," equally indicative of a failure to recognize illegal conduct and suggestive of an intent to continue it.

Defendants' conduct satisfies the four requirements for determining that future violations are likely: (1) the degree of scienter involved; (2) the recurring nature of the activity; (3) the defendant's appreciation of the wrongdoing; and (4) the defendant's opportunities to commit future violations. *See SEC v. Commonwealth Chem. Secs., Inc.,* 574 F.2d 90, 100 (2d Cir. 1978); *United States v. Webb*, 2007 U.S. Dist. LEXIS 7307, at *7 (E.D.N.Y. Jan. 31, 2007). Defendants' conduct – sales of flavored vapes – is intentional, consisting of products sales on a full-time basis. Defendants have at least constructive knowledge, and in fact actual knowledge, of the illegality of their sales under the Tobacco Control Act and the several other statutes regulating flavored ecigarettes. *See* n. 22. As established distributors they are surely in a position to continue their sales.

E. The Public Interest and the Equities Mandate Injunctive Relief

It would give short shrift to the gravity of the harm Defendants cause to assert merely that the public interest and the equities "tip," or even "tip sharply" in the City's favor. *See Robert W. Stark, Jr., Inc. v. N.Y. Stock Exch., Inc.*, 466 F.2d 743 (2d Cir. 1972) (injunctive relief requires balance of hardships "tip sharply" in plaintiffs' favor); *Lombard v. Bd. of Educ.*, 400 F. Supp. 1361 (E.D.N.Y. 1975) (same). The scales more than "tip" when there is no counterweight at all.³² Defendants can offer nothing to weigh against the public interest when in fact they are distributing a product which meets the definition of "contraband *per se.*" Demand Vape itself has argued that

³² That the distribution of flavored e-cigarettes may provide jobs, as Defendants often maintain (*Pro. Decl.* Ex. R), deserves no more countervailing weight than it would for a drug cartel, which also provides jobs. Defendants' touting of flavored e-cigarettes as a smoking cessation method is likewise of no moment where the products have never been approved for that purpose, there is no proof that flavored e-cigarettes are effective in that regard, and no proof that the purported benefit outweighs the harm of youth e-cigarette adoption.

³³ "Contraband *per se*" refers to an item that is "intrinsically illegal, the mere possession of which constitutes a crime," *United States v. Bacon*, 546 F. App'x 496, 501 (5th Cir. 2013), *i.e.*, "unlawful goods" having no lawful purpose. *See One 1958 Plymouth Sedan v. Pennsylvania*, 380 U.S. 693, 699-700 (1965) (describing certain contraband as "intrinsically illegal in character"). As stated above, no flavored e-cigarette has been authorized for sale in the

"[t]he public interest . . . does not favor rewarding parties that eschew federal regulatory requirements – like FDA premarket authorization" *Pro. Decl.* Ex. G at 28. Surely, to allow Defendants' conduct to continue instead of enjoining it would be that reward. The City seeks to protect the health and safety of its residents by enjoining the flow of flavored e-cigarettes into the City, a public purpose enshrined in City law – Ad. Code 17-715 – which prohibits the distribution, sale or offering of those products. The City's interest in obtaining preliminary relief is accordingly far greater than Defendants' interest in continuing to earn income from the distribution of contraband *per se* into the City.

The presumption that the legislature's enactment of a statute making specific conduct unlawful stands as a determination "that such conduct, in and of itself, is harmful to the public." *Golden Feather*, 597 F.3d at 121. The only permissible conclusion following from that presumption is that the public interest is served and the equities favored by a government seeking to restrain a statutory violation. Defendants can offer no legitimate public benefit from conduct barred by local, state law and federal law. There is surely no equity in allowing that conduct to continue.

United States, https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-two-vuse-solo-menthole-cigarette-products ("tobacco-flavored e-cigarette products and devices, ... are the only e-cigarettes that currently may be lawfully sold or distributed in the U.S.") and hence they cannot presently be possessed for a legal purpose anywhere in the United States.

CONCLUSION

For all the reasons set forth above, the City of New York respectfully requests that the Court issue a preliminary injunction pursuant to Federal Rule of Civil Procedure 65 enjoining Defendants from delivering into or selling in New York City flavored e-cigarettes.

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