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How state and local affirmative litigation can rein in illicit flavoured e-cigarettes

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INTRODUCTION

FDA enforcement of e-cigarette regulations is widely regarded as failing.¹ Because e-cigarettes meet the definition of a ‘new tobacco product’, to legally market an e-cigarette in the USA, a manufacturer must submit a premarket tobacco product application (PMTA) to the FDA and receive a written marketing order.^{2,3} E-cigarettes that are marketed without an FDA marketing order are considered adulterated, misbranded and unlawful.^{2,3} The FDA has issued marketing orders authorising the legal sale of 34 e-cigarette products and devices, including four menthol-flavoured products,⁴ and has denied applications for more than 26 million products.⁵ But even in the absence of more FDA PMTA marketing orders, virtually any visit to a vape shop, convenience store or gas station nationwide reveals open displays of hundreds of brands of flavoured e-cigarettes.^{6–9} Except for the four menthol products with FDA marketing orders, every single brand of flavoured e-cigarette lacks FDA authorisation.^{2,3} In localities that ban the sale of flavoured e-cigarettes, marketing them violates local laws as well.^{7,9,10} Despite FDA efforts to reduce non-compliance, including the creation of a multiagency task force, responsibility for the perceived enforcement failure is principally directed at the FDA.^{9–11} Given the appeal and widespread availability of flavoured e-cigarettes, it is difficult to envision the FDA single-handedly achieving a compliant marketplace.¹² This paper suggests that state attorneys general and local law departments could collectively use affirmative litigation to enforce existing laws and chart a course towards a compliant e-cigarette market.

Efforts to understand the details of the dynamic marketing and distribution of e-cigarettes are in early stages. An estimated 90% to 95% of the e-cigarettes sold in the USA are believed to be manufactured in Shenzhen, China.^{13,14} E-cigarettes are shipped by air and sea to US ports, where they must pass through customs controls, principally at Chicago and Los Angeles.¹⁴ In 2024, US Customs and Border Patrol seized 3.2 million e-cigarette products, valued at more than US\$81.5 million.¹⁵ Nevertheless, the wide availability of e-cigarettes suggests that Chinese manufacturers vastly under-report their US sales, defrauding the federal government of millions of dollars in import duties. According to law enforcement and private sources, e-cigarette manufacturers frequently evade federal import restrictions for e-cigarettes through false documentation misidentifying products as battery chargers, flashlights or other products

or by understating quantities or values, thereby reducing the taxes, duties and fees owed.^{14,16} When e-cigarettes are shipped into the U.S., they are first cleared through customs, and then freight forwarding companies ship the e-cigarettes to U.S.-based “master distributors” that, in turn, distribute the products to smaller regional sub-distributors and directly to retailers.¹⁴

The characteristics of illicit e-cigarettes are trending in dangerous directions. Between 2017 and 2022, the e-liquid capacity of disposable e-cigarettes quintupled to 5.7 mL, and the average strength of e-liquids tripled to 5% nicotine.¹⁷ At the same time, the average price per millilitre of e-liquid decreased threefold.¹⁷ Additionally, some newly released e-cigarette devices feature youth-friendly video games like Pac-Man.¹⁸

AFFIRMATIVE LITIGATION AND THE RISE OF E-CIGARETTES

States and local governments have historically played an important role in tobacco control.¹⁹ Congress confirmed and expanded that authority in the 2009 Tobacco Control Act, which carefully narrowed federal pre-emption of state and local efforts.^{2,20} In affirmative litigation, a government entity is the plaintiff that initiates the lawsuit. In the 1990s, a wave of tobacco litigation included state government-led affirmative litigation that recouped billions of dollars and changed industry-wide business practices.²¹ The states of Mississippi, Minnesota, Florida and Texas, through their offices of the state attorney general, blazed a trail by commencing lawsuits and eventually entering into settlement agreements with the four then-largest US tobacco manufacturers.²² These agreements paved the way for the landmark 1998 Master Settlement Agreement (MSA), among attorneys general from 46 states, and other jurisdictions, and the same four tobacco manufacturers.^{23,24} The tobacco industry made numerous marketing concessions in these lawsuits, and in the MSA alone, the industry has paid more than US\$165 billion to the states, some of which funds public health efforts.²⁵ Despite the MSA’s undeniable achievements, one of the major criticisms related to it is that most states spend a small fraction of MSA settlement funds on tobacco prevention and cessation programmes.²⁶

On the e-cigarette front, using an innovative design and youth-targeted marketing, Juul surged in popularity to the point that it dominated 75% of the e-cigarette market by 2018.²⁷ The Massachusetts Attorney General and others started investigating Juul in 2018.²⁸ Under pressure from the



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FDA and attorneys general, Juul withdrew most of its flavoured e-cigarettes from the market in 2019.²⁷ Early in 2020, the FDA announced an enforcement policy that targeted only cartridge-based e-cigarettes, like Juul, and exempted disposable e-cigarettes.²⁹ In 2020, Massachusetts filed a lawsuit against Juul based on its marketing and sale of e-cigarettes to minors, and before long dozens of other state attorneys general followed suit.²⁸ Those lawsuits led to major settlements, starting with North Carolina in 2021 and including a 33 state settlement in 2023, requiring Juul to pay a total of more than US\$1.1 billion and to change its marketing practices.^{28–30} Concerns about the allocation of settlement funds, in light of the MSA aftermath, spurred health groups to urge states to use all of the settlement funds for tobacco prevention and cessation.²⁸ The Juul settlements have also been criticised because Juul had voluntarily agreed in 2019 to various marketing restrictions, and it had been abiding by the FDA's enforcement policy since 2020.²⁸ Perhaps more importantly, by targeting Juul, which was the dominant market leader in 2018 and to a lesser extent afterwards, the FDA and attorneys general created an opening for opportunistic competitors. Unrestrained by comparable FDA oversight or attorney general lawsuits, Puff Bar began manufacturing flavoured disposable e-cigarettes that mimicked Juul's design and nicotine delivery, and other copycats followed suit.³⁰ Currently, the e-cigarette market is dominated by an ever-changing array of illicit e-cigarette brands that lack marketing authorisations, nearly all of which are disposable and flavoured.⁶

AFFIRMATIVE LITIGATION IN NEW YORK CITY

New York City (NYC) has a history of using affirmative litigation to protect public health.³¹ Early in Michael Bloomberg's first term as NYC's mayor, his health commissioner, Dr Thomas Frieden, made tobacco control a priority, and cigarette tax hikes were a central part of the plan.³² Tax increases are not only proven to decrease tobacco use but also foster tax evasion.³³

To deter cigarette tax evasion, New York City's Law Department has filed numerous lawsuits, targeting trafficking schemes involving smoke shops on Native American Indian Reservations and retailers in low-tax states that were aided by shippers, including UPS, FedEx and the US Postal Service.^{34–37} The lawsuits stated claims under federal laws, including the Contraband Cigarette Trafficking Act, Prevent All Cigarette Trafficking (PACT) Act and Racketeer Influenced and Corrupt Organizations Act (RICO) as well as claims under state and local laws.^{38–40} As a result, New York State and New York City recovered many millions of dollars—including US\$98 million from UPS and US\$35 million from FedEx—and secured concessions in settlement agreements intended to prevent future trafficking.^{41–43}

LAWSUITS AGAINST E-CIGARETTE DISTRIBUTORS IN NEW YORK CITY AND ELSEWHERE

It is difficult to measure the scale of the market for illicit e-cigarettes in New York City. Approximately 2600 retailers have an NYC retail licence to sell e-cigarettes. Unlicensed retailers selling e-cigarettes are more difficult to quantify. An Altria-funded study that examined e-cigarette packaging littered in NYC found 98.6% of the packages to be exported from China, 99% of which were flavoured.⁴⁴ This study suggests that—whether e-cigarettes were sold from licensed retailers or not—more than 90% of the littered packs lacked FDA authorisation. Similarly, the Truth Initiative published a study of nationwide data that found that 86.3% of e-cigarettes on the market lack FDA marketing authorisations.⁴⁵

Enforcement against the sale of illicit e-cigarettes has been compared with a game of whack-a-mole.⁶ When FDA takes enforcement action against certain brands, other brands replace them.⁶ Similarly, if law enforcement shuts down a retail dealer for selling illicit e-cigarettes in one location, the sales pop up elsewhere. Affirmative litigation targeting the upstream distribution chain may stand a better chance of limiting illicit e-cigarette supplies downstream than enforcement efforts that focus on the retail level.

On 10 July 2023, New York City filed a complaint naming several national e-cigarette distributors as defendants, *City of New York v. Magellan Technology, et al* ('Magellan').⁴⁶ The City has since filed a second lawsuit against local distributors⁴⁷ and a third suit against an online e-cigarette seller.⁴⁸ In doing so, the City is targeting some of the primary sources of e-cigarettes at the distribution level. Distributors of e-cigarettes can be identified through PACT Act registration forms, and many distributors do register with the Department of Justice and state tax administrators.⁴⁹ By naming e-cigarette distributors—not manufacturers—as defendants, the *Magellan* complaint avoids legal obstacles regarding actions against the largely overseas manufacturers.

Although the City's lawsuits are in their early stages, it is useful to highlight several enforcement mechanisms that are available to states and localities. The PACT Act, which was amended in 2020 to cover e-cigarettes, provides strong federal remedies for e-cigarette trafficking, including injunctive relief and substantial penalties.³⁹ Recent rulings in *Magellan* suggest that the PACT Act will be a significant enforcement tool. For example, the PACT Act imposes steep penalties on e-cigarette sales but exempts from liability sales by tobacco businesses that are 'lawfully operating'. The *Magellan* court sensibly rejected the notion that the phrase 'lawfully operating' was meant merely to cover distributors making sales to licensed tobacco businesses. Instead, it held that the term means businesses that are more broadly 'in compliance with the law', which include laws banning the sale of flavoured e-cigarettes. Under the PACT Act, sellers of e-cigarettes are required to comply with the applicable laws of any jurisdiction into which they are shipping products; thus, a distributor shipping flavoured e-cigarettes into a jurisdiction that prohibits their sale is violating both the PACT Act and the local flavour ban. Moreover, although *Magellan* deals with shipments into New York City, which has a flavour ban, the court's rationale suggests that the PACT Act's 'lawfully operating' requirement applies with equal force against a distributor shipping adulterated and misbranded e-cigarettes that lack FDA authorisation.

The *Magellan* court also confirmed that any state can bring PACT Act lawsuits, finding that a jurisdiction imposing a tax on conventional cigarettes, including a sales tax, has standing to sue under the PACT Act. The court rejected an argument that PACT Act standing is limited to jurisdictions that tax e-cigarettes. Since all states impose a cigarette excise tax, it follows that any state attorney general—and municipalities that tax cigarettes—can use the PACT Act to sue unlawfully operating e-cigarette distributors.

On 20 February 2025, New York's Attorney General filed a lawsuit in the Southern District of New York against 13 major e-cigarette manufacturers, distributors and retailers for their role in making e-cigarettes accessible to youth.⁵⁰ Notably, this case names as defendants, *Magellan* and other parties to New York City's *Magellan* lawsuit as well as several of the largest e-cigarette distributors in the USA.

The PACT Act is by no means the only cause of action available for state and local actions against e-cigarette sellers. Under

settled federal law, if e-cigarette sellers fail to provide reports of shipments, they may be liable for mail or wire fraud, which, in turn, supports a civil action under the RICO statute.⁵¹ State delivery statutes, like New York's, which prohibit e-cigarette deliveries to consumers, provide another enforcement tool.⁵² Given the success of public nuisance actions against Juul in a multidistrict litigation case, *In re Juul Labs*, taking place in California, common law public nuisance suits may be available against flavoured e-cigarette sellers.^{46 53} Common law public nuisance is a legal theory that can support a lawsuit regarding a product that harms the health and safety of a large number of persons within a state. Vermont's Attorney General recently settled a lawsuit with Amazon for US\$400 000 for shipping tobacco products, including e-cigarettes, directly to Vermont consumers.⁵⁴ Like *Magellan*, the Vermont case targets the chain of distribution.

California's Attorney General has demonstrated leadership on this front as well. In January, California commenced a lawsuit against several defendants for illegally importing FLUM e-cigarettes, which lack FDA authorisation, from China and distributing them in California.⁵⁵ Also in January 2025, Illinois' Attorney General filed a lawsuit against businesses responsible for distributing Posh e-cigarettes, one of Illinois' bestselling disposable e-cigarette brands, which lack FDA marketing orders.⁵⁶ While this highlights several comparable attorney general lawsuits, it does not exhaustively list state and local law enforcement activity regarding illicit e-cigarette distribution.⁵⁷

In a similar context, in December 2024, the attorney general's office for the District of Columbia—which banned the sale of flavoured tobacco products, effective October 2022—entered into a settlement for US\$1.2 million with Swedish Match North America, which is owned by Philip Morris International, regarding online sales of flavoured Zyn nicotine pouches to consumers in the District of Columbia.⁵⁸ The settlement requires Swedish Match to monitor distributor compliance and to send annual compliance reminders to distributors and retailers.⁵⁸

Importantly, state attorneys general have inherent power to protect public health. The MSA is the most obvious historical example of that power, and the Juul settlements for more than US\$1.1 billion validate that approach. Affirmative litigation may be crucial to protecting youth from unregulated addictive e-cigarettes, and at the same time, enabling the FDA to effectuate a central part of its regulatory power. This litigation strategy is also likely to prove to be a more effective use of limited government resources than focusing on retail enforcement.

The Big Cities Health Coalition, representing public health leaders from 24 cities, underscored the importance of this issue to local jurisdictions nationwide. In a letter to the FDA, they requested more help with the widespread availability of illicit e-cigarettes, explaining that big cities are enforcing their laws but need help on a national level.⁵⁹ To the extent smaller localities lack the resources for litigation, private law firms have in the past shown interest in assisting cities with public health litigation, either *pro bono* or on a contingent fee basis. Also, local jurisdictions may find opportunities to partner with their state attorneys general.

CONCLUSION

There seems to be general agreement in at least some public health circles that public health would be well served if the domestic e-cigarette market could be cleared of e-cigarettes that lack FDA authorisation. A coalition of federal, state and local

law enforcement authorities working collectively, as they have before, may have a chance of achieving that goal.

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