



Illicit Trade of ENDS Products: Addressing a New Black Market

Combatting Illicit Trade: Adapting Enforcement to New Challenges
TMA Digital Conference

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Negative Public Health Impact of Black-Market ENDS Products

Present Additional Health and Safety Risks



- Lack product characterization and adherence to consistent manufacturing practices
- Produced under unknown quality controls and standards, with unknown ingredients
- Ability to modify or tamper with products

“

Additional risks posed by these products include the potential that they contain harmful chemicals or constituents that are not present in other products that they are manufactured using comparatively poor quality controls, and that they are designed in ways that facilitate modifications by distributors or users – all of which increase the risk of adverse events.”

”

– FDA, Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)* (April 2020)

Undermine Underage-Prevention Measures

- Marketed with “youth-appealing” labeling and packaging and in flavors restricted by Enforcement Priorities Guidance
- Sold through nontraditional retail channels that contribute to underage access – e.g., online marketplaces with little to no age-verification and social sourcing



FDA's Comprehensive Enforcement



ENFORCEMENT PRIORITIES GUIDANCE

- Any flavored, cartridge-based ENDS product other than tobacco and menthol flavors
- All other ENDS products for which the manufacturer fails to take adequate measures to prevent minors' access
- Any ENDS product that is targeted to minors or whose marketing is likely to promote use by minors
- Emphasis on illicit, black-market ENDS, including counterfeit, compatible, and diverted products, that present additional health and safety risks to consumers beyond those of authentic products



WARNING LETTERS

- In September 2019, Warning Letter to Eonsmoke for marketing nearly 100 ENDS, including unauthorized compatible products, without premarket authorization
- Since February 2020, over 175 Warning Letters to manufacturers, distributors, and retailers for illegally marketing ENDS, including JUUL-compatible products, in violation of Enforcement Priorities Guidance and/or without premarket authorization
- 10 Warning Letters to manufacturers and retailers that sold ENDS products targeted to minors or likely to promote use by minors



IMPORT ALERTS

- **Import Alert 98-06:**
New tobacco products imported and marketed without premarket authorization
 - Eonsmoke on "Red List"
- **Import Alert 98-07:**
ENDS products imported and marketed in violation of Enforcement Priorities Guidance
 - RELX on "Red List"

Importance of ongoing enforcement through Sept. 9, 2020 and transparency on PMTA process for currently marketed products for states, distributors, retailers, and adult consumers

Defining the Product Types of Illicit ENDS

Counterfeit Products



Designed and marketed to mimic authentic ENDS products

Made and distributed by unauthorized manufacturers

Largely imported from China

Unauthorized Compatible Products



Designed and marketed to be used with authentic ENDS products without the manufacturer's authorization

Marketed and sold with e-liquid formulations containing nicotine or other substances, including THC, and empty for users to fill and refill

Diverted Products

Health

JUUL's 'Banned' Flavors Are Still Absolutely Available in New York City

Convenience and vape stores in the city somehow continue to stock the flavors JUUL said it would remove last year.

Nov 4 2019, 2:00pm [Share](#) [Tweet](#) [Snap](#)



Authentic ENDS products that are intended for and sold in non-U.S. markets but have been imported into the U.S. without the manufacturer's authorization

Counterfeit Products

Global distribution across channels requires collaboration among industry, governments, and law enforcement



**Ex-U.S. Manufacturing
(China)**

Raid of
Chinese warehouse



Cross-Border Import

Detained at
U.S. Customs & Border Protection facility



**U.S. Commerce
(Wholesale/Retail)**

Seizure at
Georgia retailer

Unauthorized Compatible Products

Third-party products without premarket authorization that have proliferated since 2018

Since 2018, the market has seen a significant uptick in the availability and sales of unauthorized “JUUL-compatible products”

Likely introduced well after August 8, 2016, without premarket authorization

Sold primarily at independent retailers and online with lax age-verification compliance

Available with nicotine, other substances, and empty to be filled and refilled by users

Third-party, unlicensed manufacturers are marketing cartridges as “compatible” with the JUUL System

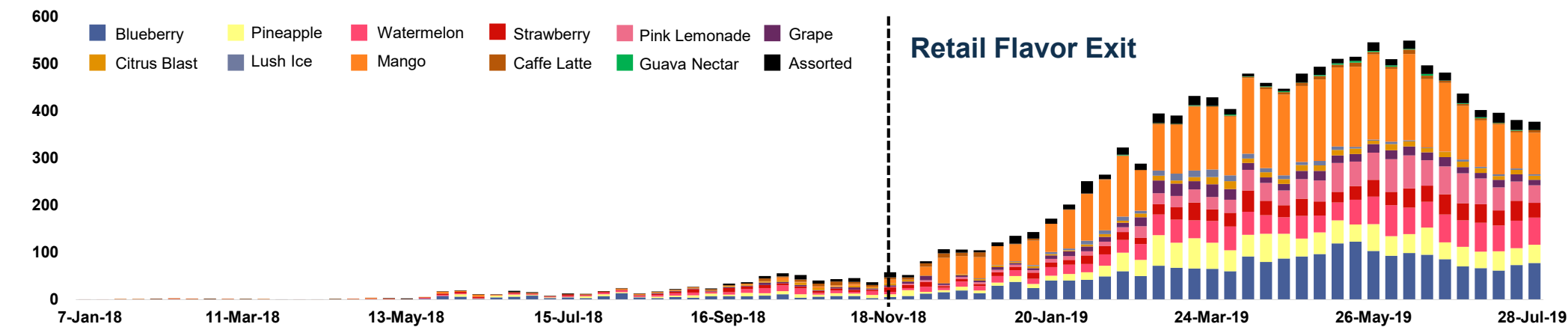


Unauthorized compatible products are sold in a variety of packaging presentations and flavors, with unknown and untested ingredients

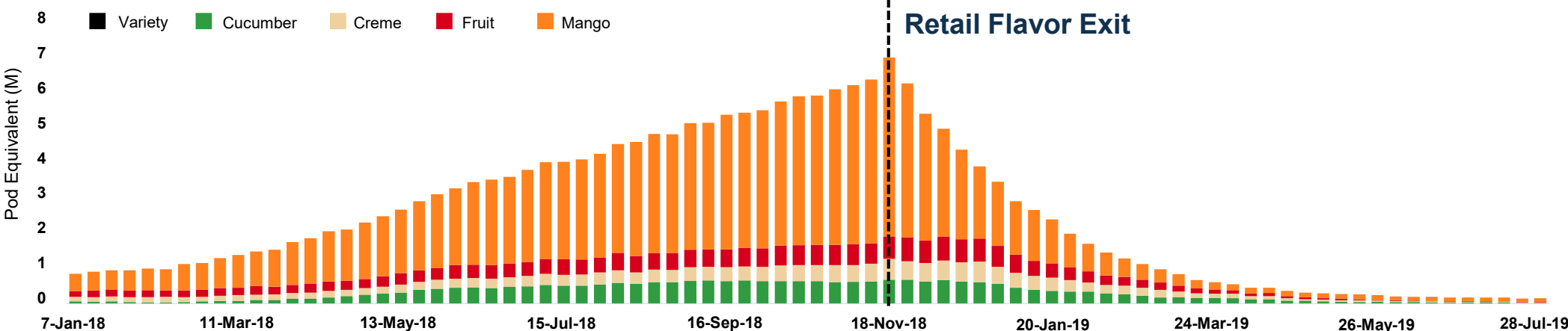
Unauthorized Compatible Products

Case study on the market impact of voluntary flavor restrictions

Eonsmoke
Unauthorized
“Compatible”
Pods by NTM
Flavor



JUULpods by
NTM Flavor



Summary of Juul Labs' Global Enforcement Functions



BRAND PROTECTION

**Intelligence gathering on
illicit-trade networks**

**Disable illicit-distribution system
among producers and resellers**

Interdiction at points-of-entry

Online enforcement and take-downs







INTELLECTUAL PROPERTY

**Patent prosecution against
infringing products across
the distribution system**

**Global anti-counterfeiting
enforcement**

**Trademark enforcement and
domain-name recovery**

Examples of Brand Protection Enforcement

	2019	2020 (YTD)
 Customs Enforcement	500+ seizures of black-market JUUL products (U.S. and ex-U.S.) 57 seizures at U.S. points-of-entry	20+ seizures of black-market JUUL products (U.S. and ex-U.S.) 8 seizures at U.S. points-of-entry
 Online Enforcement	84,000+ product listings of illicit JUUL products removed from online retailers and platforms	60,000+ product listings of illicit JUUL products removed from online retailers and platforms
 Investigations	2,600+ investigations of distributors and retailers selling black-market JUUL products	3,300+ investigations of distributors and retailers selling black-market JUUL products
 Operations/Legal	700+ C&D letters to distributors and retailers for selling black-market JUUL products	270+ C&D letters to distributors and retailers for selling black-market JUUL products

Additional Programs



Audit

Conduct review of underage-prevention impacts



Intelligence

Develop actionable information to target illicit suppliers and sellers

Examples of Intellectual Property Enforcement

ITC Action 1 (1139 Investigation)

October 3, 2018

JLI requested an investigation into ENDS manufacturers, importers, distributors, and retailers relating to unauthorized JUUL-compatible products, including Eonsmoke and 4X products

April 20, 2020

ITC issued Final Determination, Limited Exclusion Order (LEO), and Cease and Desist Order (CDO) against Eonsmoke and another party that had defaulted

Market Impact

Eonsmoke was ordered to stop importing, selling, marketing, advertising, and distributing all “nicotine vaporizer devices and the associated pods sold for use with the device” that infringe on JLI patents

ITC Action 2 (1141 Investigation)

November 20, 2018

JLI requested an investigation into multiple entities for the manufacture, import, and sale of unauthorized JUUL-compatible products

April 7, 2020

ITC issued Final Determination, LEOs, and CDOs against 4 defaulting parties, barring them from continuing to import and sell infringing products in the U.S.

Market Impact

15+ entities agreed to stop importing infringing products through negotiated settlements or consent orders; remaining (defaulting) entities barred from importing and selling infringing products

Continued Collaboration Across Stakeholders to Address Black Market



Industry

- Adoption of global brand-protection units to identify sources of illicit trade and facilitate enforcement, including against IP-infringing products
- Shared information and resources with law-enforcement agencies



Federal

- Increased funding and resources for regulatory and border enforcement
- Coordination and training with state and local law enforcement



State and Local

- Implementation of state-level registries for legally marketed products, including status of PMTA submissions during “transitory period”
- Expanded enforcement against violative distributors, wholesalers, and retailers



Public Health

- Research and testing of counterfeit and compatible products
- Additional focus on marketing tactics (e.g., social media) and illegal online sales and social sourcing