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THE KEY TO CONSUMER SAFETY:

DISPLACING THE **ILLICIT CANNABIS MARKET**
RECOMMENDATIONS FOR SAFE VAPING



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1. INTRODUCTION AND NCIA'S SAFE VAPING TASK FORCE

As reports began to appear of a potential linkage between lung injuries and use of nicotine and/or cannabis vaping products, NCIA's Policy Council established a Safe Vaping Task Force to provide a consistent response on behalf of the concerned members of the regulated cannabis industry. The Task Force's mission was to communicate clearly in response to press reports and governmental actions, and articulate the state-legal cannabis industry's fulsome efforts to act with integrity as responsible actors. The Task Force produced and published weekly blogs summarizing recent developments and the cannabis industry's response; drafted Congressional testimony for a Senate Health, Education, Labor and Pensions (HELP) Committee hearing on November 13, 2019; drafted op-eds; collaborated with other safe vaping efforts, including in California; and started the planning for a summit in Boston on February 19, 2020 to facilitate collaboration between law enforcement and the private sector to tackle the illicit market through public-private partnerships.

The Task Force's efforts transitioned to a new phase in late November when health experts confirmed that the proximate cause of many of the injuries and deaths were attributable to vitamin E acetate used as a thinning agent in illicit market products. With a diminished need to provide rapid response to the misleading data points appearing in reports of this crisis, our work began to focus squarely on a long-term solution. Below are recommendations from the Task Force regarding safe vaping. By offering this industry subject matter expertise, it is our hope that consumers, retailers and government agencies will become better informed as a result of our collective efforts.

Today, it appears that public health experts have concluded that additives from the illicit market appear to be the primary cause

of this crisis.¹ While that work continues, we attempt to clear up some of the myths that exist about vaping cannabis oil and offer explanations for other potential dangers and strategies for minimizing risk.

Ultimately, one thing is clear: we must stop the flow of unregulated and untested products to consumers from the illicit market. That is the best solution to the vaping crisis, which is not likely to dissipate unless we take swift action to put illegal and unscrupulous operators out of business. That effort will take a collaborative approach, with law enforcement, state-legal cannabis businesses, state cannabis taxing and licensing agencies, providers of anti-counterfeiting technology and others working in concert. Information sharing between the public and private sectors here will be key. And while we must disrupt the illicit market, we need to identify alternatives to arrest and prosecution and we must create reasonable paths to state licensure. It will take forward-looking elected and appointed leaders to make sure that we displace the illicit market, while remembering that the industry made 12 billion dollars in 2018 while approximately 600,000 people were arrested for marijuana-related arrests.² Fundamental fairness must play a role in any solution to the illicit market problem. We need to evaluate and refine state regulations by encouraging smart regulation at the state level, such as the banning of certain additives as seen in Colorado. States must continue evaluating what is necessary to keep consumers safe and implement appropriate regulations. In the end, sensible regulation and a clear path to licensure and compliance will be the utmost compelling force in driving people from the illicit market to the state-legal market.

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1. On January 14, 2020, the Centers for Disease Control (CDC) issued an update on the vaping crisis. The CDC study found that 78% of people who became ill reported using THC products purchased from the illicit market. Sixteen percent reported purchasing from "commercial sources," including "pop up" stores and vape shops, which do not necessarily reflect legal, licensed operations. While state-legal dispensaries are required to sell only regulated products that have been lab tested, "pop up" stores and unregulated "vape shops" are not subject to the same scrutiny as state-legal dispensaries. In addition, this data is based on self-reports, which the CDC concedes is often inaccurate and subject to "social desirability bias." The Policy Council believes that consumers are safer when purchasing from the state-legal regulated market. *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, CENTERS FOR DISEASE AND CONTROL PREVENTION (last reviewed Jan. 14, 2020), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

2. The Policy Council understands that the word "marijuana" sometimes connotes historical racism, particularly for people who have been negatively affected by the "war on drugs." We use the term "marijuana" (rather than "cannabis") to distinguish between intoxicating forms of cannabis containing THC and non-intoxicating low-THC cultivars of cannabis considered "industrial hemp," and because this term is codified in federal law.

2. ACKNOWLEDGEMENTS



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"...there are currently no federal requirements regarding grade of ingredients in inhalable cannabis products. The lack of sufficient safety studies on inhaling the ingredients included in vapes also complicates the situation. Therefore, it is important for manufacturers to do their due diligence, invest in research and source suitable materials for their products."



3. DISPLACING THE ILLICIT MARKET

The Cannabis Industry has a Serious and Disruptive Illicit Market Problem

The cannabis industry has a serious and disruptive illicit market problem that is directly affecting public health and safety. Indeed, in California, illegal retailers outnumber licensed and regulated marijuana businesses to a ratio of approximately 3 to 1.³ In Massachusetts, 75% of all cannabis sales in 2019 are expected to be from unlicensed sources.⁴ Outside of the United States, Canada, is also struggling with its own cannabis illicit market problems, despite allowing adult use of marijuana at the federal level.⁵

The illicit market has continued to flourish for a number of reasons. First, high taxes imposed on compliant operators and their customers handicap a licensee's abilities to effectively compete against illegal operations and encourage consumers to shop at unlicensed shops. Second, cities' and counties' unwillingness to either open their local jurisdiction to licensed commercial cannabis activities or issue enough retail licenses to satisfy local demand has compelled certain experienced actors in the industry to enter the underground market. Finally, the current level of law enforcement is ineffective at either deterring illegal actors or meaningfully disrupting the underground cannabis industry as a whole. Therefore, in order to permanently displace cannabis's illicit market, regulators must lower taxes on compliant businesses and their customers, work to expand the market by providing a licensure pathway to unlicensed operations, and re-shift focus from raiding illegal retail storefronts to permanently dismantling illicit cultivation operations.

High Taxes Contribute to the Growth of the Illicit Market

Cripplingly high state and local tax rates imposed on compliant operators and consumers have unwittingly contributed to the expansion of the illicit market by handicapping licensees' ability to compete with the illicit market while also increasing the demand for cheaper cannabis, thus further encouraging the rapid growth of the illicit market.

In California, for example, legal operators face local, state, and federal taxes—including, but not limited to, regular sales taxes, an additional 15% excise tax on retail cannabis sales, and additional wholesale taxes on cannabis biomass that are due to increase once again in 2020.⁶ Illegal operators pay no tax and avoid the substantial costs that come with being compliant under state and local regulations. This imbalance prevents a legal operator from being able to meaningfully compete against its underground counterpart.

Industry experts estimate that California cannabis illicit market's revenue in 2019 will be about \$8.7 billion, as opposed to the \$3 billion revenue generated by the legal vendors.⁷ This stark difference illustrates the extreme burden high taxes can have on legal operators as the price of legal cannabis goods continue to climb, which in turn fuels the demand for cheaper cannabis and inevitably the expansion of the illicit market. It is no wonder that California, a state with the highest legal marijuana taxes in the country, is also struggling to contain an out of control illicit market that the Los Angeles Times has deemed to be the largest in the world.⁸ A finding conducted by the United Cannabis Business Association in September 2019 concluded that there are more than three times as many illicit market retailers as there are licensed storefronts or delivery services combined in California, further illustrating the problems that result from excessive taxation of the industry.⁹

Imposing high taxes on cannabis may also backfire and cause significant financial harm to the state in the form of loss of taxation revenue. In California, annual cannabis tax of more than \$1 billion was projected to be collected by 2018. However, only about \$345 million was actually collected; additionally, the Governor's Office has projected that the state expects to collect only \$479 million in fiscal year 2019-2020 and \$550 million in fiscal year 2020-2021. The illicit market is commonly cited as one of the primary reasons for the substantial gap between what was anticipated and actually collected.¹⁰

3. Dennis Romero, *California's cannabis black market has eclipsed its legal one*, NBC NEWS (Sept. 20, 2019, 2:01 AM), <https://www.nbcnews.com/news/us-news/california-s-cannabis-black-market-has-eclipsed-its-legal-one-n1053856>.

4. Kevin Murphy, *Cannabis' Black Market Problem*, FORBES (April 4, 2019, 1:30 PM), <https://www.forbes.com/sites/kevinmurphy/2019/04/04/cannabis-black-market-problem/#3d97cb41134f>.

5. Sean Williams, *Canada's Black Market to Control 71% of Marijuana Sales in 2019*, THE MOTLEY FOOL (Feb. 9, 2019, 6:36 AM), <https://www.fool.com/investing/2019/02/09/canadas-black-market-to-control-71-of-marijuana-sa.aspx>.

6. Cannabis Special Notice from California Department of Tax and Fee Administration, Cannabis Rate Changes Effective January 1, 2020. Retrieved from: <https://www.cdtfa.ca.gov/formspubs/L720.pdf>.

7. Scott Shackford, *The marijuana black market will keep its throne in California*, thanks to tax increases, REASON.COM (November 25, 2019, 2:05 PM), <https://reason.com/2019/11/25/the-marijuana-black-market-will-keep-its-throne-in-california-thanks-to-tax-increases>.

8. Patrick McGreevy, *California now has the biggest legal marijuana market in the world. Its black market is even bigger*, LOS ANGELES TIMES (Aug. 15, 2019, 5:00 AM), <https://www.latimes.com/california/story/2019-08-14/californias-biggest-legal-marijuana-market>.

9. Sean Williams, *California's Cannabis Black Market Is Insanely Larger Than Its Legal Market*, THE MOTLEY FOOL (Sept. 14, 2019, 10:51 AM), <https://www.fool.com/investing/2019/09/14/californias-cannabis-black-market-is-insanely-larg.aspx>.

10. Scott Zamost, et al. *A look inside the black market for weed shows the huge threat to legal businesses*, CNBC (July 12, 2019, 7:36 AM), <https://www.cnbc.com/2019/07/11/las-black-market-for-weed-threatens-the-growth-of-its-legal-business.html>.

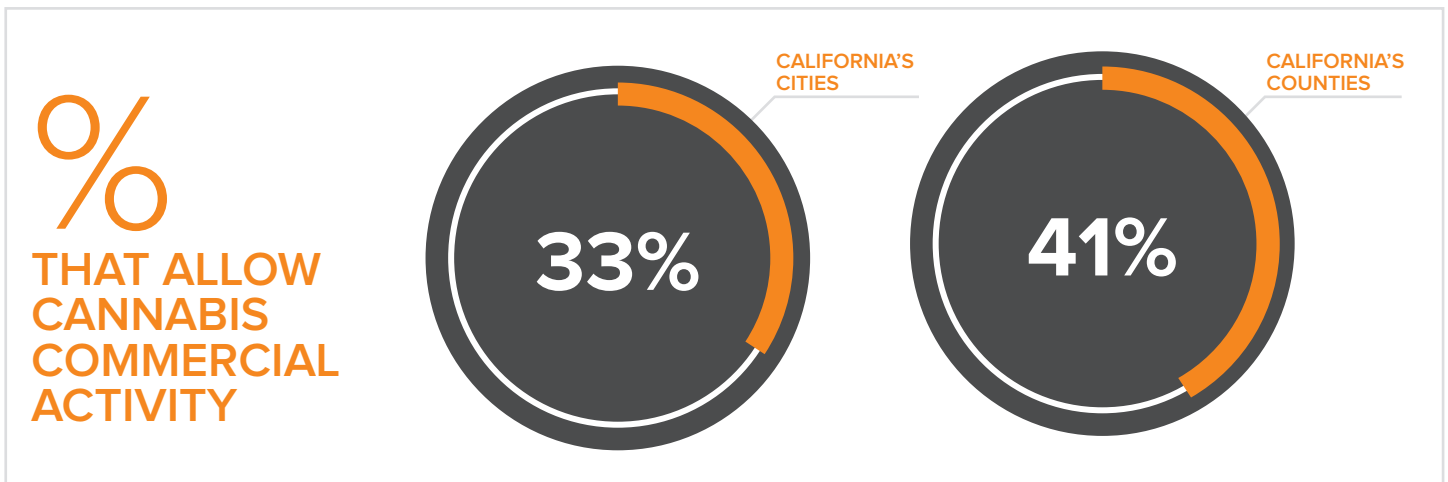
The imposition of high taxes on the cannabis industry benefits the illicit market, plain and simple. High taxes inevitably lead to higher prices in legal cannabis and in turn forces consumers to turn to illicit stores for cheaper cannabis products. This in turn pushes cannabis transactions into the illicit market and thus leads to loss of tax revenue. The massively disproportionate size of the illicit market relative to the legal market, and the loss of substantial tax revenues demonstrates the dire need to lower taxes on this burgeoning industry.

Providing Licensure Pathway to Unlicensed Operations Will Stunt the Illicit Market

In conjunction with lowering taxes, regulatory agencies in cities and counties should also consider opening their local jurisdiction to licensed commercial cannabis activities and implement a pathway to licensure for illegal operators. This approach is crucial to the success of the regulated market, as the conversion of illegal operators into compliant licensees will stunt the growth of the illicit market by reducing the number of underground operators, removing unregulated and unsafe products from the stream of commerce and boosting state and local tax revenues.

previously established medical marijuana market were unable to obtain the city or county licenses they need to continue their livelihood.¹² As a result, many of these experienced legacy operators have made a Hobson's choice and have continued operation without licenses, thus contributing to the expansion of the illicit market. And because these operators have been navigating through California's quasi-legal medical market for the past two decades, they are extremely well versed in operating their cannabis business under the radar, further solidifying the illicit market's grip on the cannabis industry and unwitting consumers.

Providing a licensure pathway to these legacy operators seasoned in the industry will accelerate the conversion of experienced actors in the illicit market into legal businesses. This in turn should stunt the expanding illicit market as more veteran underground operators become licensed and convert their operations to the legal market. Such conversion will achieve two purposes. First, it will decrease the supply of unregulated cannabis products entering the stream of commerce, as vendors who were once purveyors of these products turn to supplying the regulated market instead. Second, as more operations join



Despite the passage of Adult Use of Marijuana Act and the establishment of a state licensing regime, only about 33% of California's cities and 41% of California's counties allow cannabis commercial activity; some not only prohibit the establishment of cannabis retail storefronts within their borders, they also prohibit the delivery of regulated cannabis by licensed businesses lawfully established in other local jurisdictions.¹¹ Furthermore, certain cities and counties that are opening their doors to the industry limit the types of commercial cannabis activities that are allowed within their borders, making interested parties' participation in the legal market all the more restrictive. Consequently, many legacy operators from the state's

the licensed market, state and local tax revenue will increase because otherwise un-taxable operations and transactions will become taxable as part of the conversion. Consequently, opening up more local jurisdictions and having more cannabis licenses available will ultimately benefit consumers, state and local governments, and the licensed market.

Focused Enforcement Efforts Will Shrink the Illicit Market

As part of the strategy to combat the illicit market, California and other enforcement agencies must continue aggressive raids and other enforcement actions on unlicensed cannabis businesses. In the last year alone, enforcement efforts on unlicensed stores

11. John Schroyer, et al., *Chart: Most of California municipalities ban commercial cannabis activity*, MARIJUANA BUSINESS DAILY (Feb. 18, 2019), <https://mjbizdaily.com/chart-most-of-california-municipalities-ban-commercial-cannabis-activity/>.

12. *Id.* <https://mjbizdaily.com/chart-most-of-california-municipalities-ban-commercial-cannabis-activity/>.

have tripled.¹³ These storefronts represent a clear and present danger, particularly to the unwitting consumer. Despite these shutdowns, the illicit market continues to flourish because raiding unlawful retail stores is only part of an effective strategy to stop the illicit market. Enforcement agencies should widen their focus to encompass the goal of permanently dismantling illegal cultivation sites.


Raiding illegal storefronts rarely substantially impacts the actual owner because they are usually in the shadows and workers at these stores do not know who the actual owners are.¹⁴ In addition, seasoned unlicensed operators know how to minimize the costs of opening illegal stores and rarely keep substantial amounts of cash or products on unlicensed premises, further minimizing the economic harm suffered by the owner as a result of a raid. Indeed, unlicensed stores are opening at a faster rate than the city can shut them down, and shops that have been raided often reopen.¹⁵ Thus, it is clear that raiding retail stores is an ineffective technique in combating the illicit market and regulators should focus instead on other strategies to eradicate the illicit market.

Permanently dismantling illegal cultivation sites is a crucial element on which regulators must focus to displace the illicit market, because the costs of successful cultivation are high and are difficult for unlawful storefront operators to replace after raids resulting in destruction. In addition, shutting down illegal grow operations will disrupt the supply chain to the illicit market and increase the price of unlicensed products.

Unlike opening unlicensed storefronts where there are minimal associated costs, profitable cultivations, whether indoor, outdoor or mixed light, require expensive equipment, and a substantial amount of time and experience. Cultivation sites take months to setup and the plants take many more months

to reach maturity. If a cultivation is raided at any given time before harvest, it will substantially impact the owner. If the same owner's cultivations were raided repeatedly throughout the year, it would effectively deter the owner from growing due to a lack of economic incentive. In addition, when illegal cultivations are forced to shut down, growers are unable to quickly re-grow and start supplying the illicit market immediately, thus increasing the price of illegal cannabis products. Therefore, by focusing on raiding illegal grow operations, regulators can effectively disrupt the illicit market's supply chain, forcing the price of unauthorized cannabis products to increase in order to eliminate one of the few advantages illicit market has over the licensed platform. Some local and state officials have taken reasonable approaches to enforcement by shutting off water, shutting off electricity, locking doors, and confiscating product. The Policy Council fully supports these efforts that fall short of re-criminalizing cannabis growers through arrest and prosecution, but subject the illicit operator to financial harm.

In sum, to permanently displace the illicit market, regulators must first lower taxes on compliant operations, so that legal operators have a chance to meaningfully compete against the illicit market. At the same time, applicable governing agencies must also open the market and provide a pathway to licensure for unlicensed operations. Doing so would shrink the illicit market, remove unregulated and potentially unsafe products from the stream of commerce, and boost collectible tax revenue for the government. Finally, a focus on shutting down as many illegal grow operations as possible will deter illegal cultivation owners from re-operating, seriously disrupt the supply chain to the illicit market, and force the increase in price for all illegal cannabis products, which would allow the licensed market to meaningfully compete against the illicit market.



“The imposition of high taxes on the cannabis industry benefits the illicit market, plain and simple. High taxes inevitably lead to higher prices in legal cannabis and in turn forces consumers to turn to illicit stores for cheaper cannabis products.”

13. Los Angeles Times, *California Seizes \$30 Million in Black Market Cannabis From Illegal Shops — Tripling Raids in Last Year*, KTLA (July 22, 2019, 3:05 PM), <https://ktla.com/2019/07/22/california-seizes-30-million-in-black-market-cannabis-from-illegal-shops-tripling-raids-in-last-year/>.

14. Scott Zamost, et al., *Police raid illegal weed dispensary in Los Angeles*, CNBC (Aug. 14, 2019, 10:00 AM), <https://www.cnbc.com/2019/08/14/illegal-weed-dispensary-raided-by-los-angeles-police.html>.

15. Teri Figueroa, *Raid shuts down San Diego County marijuana shop that reopened after it was ordered closed*, THE CANNIFORNIAN (May 25, 2018), <https://www.thecannifornian.com/cannabis-news/law/raid-shuts-san-diego-county-marijuana-shop-reopened-ordered-closed/>.

16. Julie Wurth, *A budding crop: Growing cannabis is labor-intensive, expensive to start, but doable*, THE STATE JOURNAL REGISTER (Aug. 12, 2019, 6:35 AM), <https://www.sj-r.com/news/20190812/budding-crop-growing-cannabis-is-labor-intensive-expensive-to-start-but-doable>.

4. COUNTERFEIT CARTRIDGES

Counterfeit and Illicit-Market Vendors are the Primary Source of Contaminated Vape Cartridges and Products

In addition to unregulated additives like vitamin E acetate, pesticides and heavy metals have been found in dangerously high amounts in illicit market products. It appears, based on these reports, that more than 2,600 people have become ill because of these counterfeit cartridges.¹⁷ Unscrupulous vape cartridge vendors perpetuate the problem by willingly and knowingly manufacturing cartridges and placing them in counterfeit packaging that has been illegally stamped with known brands from the regulated market, fake batch and serial numbers, and false testing results.

CCELL is one of the most widely recognized brands of vape cartridges with serial numbers and the logo of the exclusive distributor stamped on the inside of the base for authenticity and verification. However, there are cartridge vendors that will fulfill an order for tens of thousands of cartridges, complete with imitation CCELL serial numbers and distributor logo stamped on the base,

just like the original. As price is the primary driver for a counterfeit vendor, the cartridges are manufactured with materials that may not pass heavy metals testing. Lead-heavy components, unknown material suppliers and fake lab results validating untested cartridges are feeding and maintaining the illicit market.

Illicit market cartridges are often sold in packaging that resembles known brands. From the colors to logos and unverified lab results, all are printed and ready to fill with whichever fake cartridge can be procured. Far more insidious is the concerted effort made by packaging companies to create packaging that is specific to illicit-market vape cartridge vendors. Creative names on empty boxes, some of which are so popular that is believed to be an actual brand (like Dank Vapes), are available to buy in bulk with fake lab results printed on them. Vaporizer hardware manufacturers and distributors should have controls in place so that empty hardware is only provided to licensed businesses, which is one more way to displace the illicit market.

5. VAPORIZER LIQUID FORMULATIONS

Quality of Ingredients: Consumers Ingest What They Inhale, Making Food and Pharmaceutical Grade Components and Raw Inputs Critical

While consumers debate the merits of vaping vs. smoking/combusting cannabis flower, one fact remains constant: you are ingesting what you inhale. Therefore, NCIA's Policy Council strongly suggests that consumers only purchase regulated and tested products from the state-legal market. Products that have been tested by an accredited laboratory, and those that are regulated by a sanctioned state governmental agency, are inherently safer than untested, unregulated products from the illicit market. Below, we focus attention on safe ingredients that may be included within the vape cartridge, including pure cannabis oil (live resin).

The foundation of finished consumable products are the raw materials (ingredients, additives, etc.) used in their creation. Uncertainty about the ingredients and other raw materials in consumable products increases the potential risks to the integrity of the product itself, and ultimately to consumer safety. Ingredients and additives can be manufactured in different

grades for varying uses. Using the appropriate grade and quality of ingredients can minimize risk and increase product integrity and safety.

Low-grade ingredients are less pure, scarcely tested, and may contain undefined and/or higher levels of contaminants. On the other hand, higher grade ingredients are appropriately tested and supplied with full transparent documentation to validate their quality in the form of Certificates of Analysis (COAs). COAs include "per lot" ingredient information such as lot number, identity, purity, strength, and level of chemical and/or biological contamination. COAs are important records for manufacturers because they ensure traceability of ingredient lots and provide the supplier's test results for a specific lot of raw ingredients.

Cannabis vaporizer pens and cartridges often include several ingredients and additives in their liquid formulations, such as cannabis concentrates, cosolvents, and flavorings. Non-cannabis derived ingredients are often available in different grades and many have various applications in manufacturing non-consumables, food, pharmaceuticals and cosmetics. Two high quality examples are Food Chemicals Codex (FCC) grade

17. *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Dec. 31, 2019, 1:00 PM), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

ingredients that meet FCC standards and U.S. Pharmacopeia (USP) grade ingredients that are produced in a cGMP compliant facility and meet or exceed the USP monograph with known levels of impurities. Lower grade examples include technical or commercial grade ingredients that have purity levels around 80 - 90%.

Some grades may be equivalent, but appropriateness should always be confirmed by reviewing applicable state regulatory requirements. This is challenging for cannabis vape manufacturers because there are currently no federal requirements regarding grade of ingredients in inhalable cannabis products. The lack of sufficient safety studies on inhaling the ingredients included in vapes also complicates the situation. Therefore, it is important for manufacturers to do their due diligence, invest in research and source suitable materials for their products.

Cannabis Ingredients

The cannabis-derived ingredient in cannabis oil vaporizers is a concentrate that is produced by extracting the cannabinoids and other compounds from the plant. With the exception of supercritical CO₂ extraction, most other common extraction methods use butane, alcohol, or hexane as solvents for the extraction of cannabis oils used in vape pens. Extraction processes using these solvents may result in a small presence of the solvent in the extracted oil. Any residual solvent must ultimately be removed prior to any product being sold to consumers. States that have legalized and regulated cannabis typically have specific requirements regarding allowable concentration levels of these solvents. These states also require full analytical testing by licensed independent labs, including reporting of residual solvents, to ensure that only safe levels of any solvents are present in the final formulation of cannabis vape products.

The type of cannabis concentrate used in a vaporizer is important to consider. Some require diluents or other additives to be effectively vaporized while other types of concentrates (eg: live resin) have the appropriate viscosity to be used in vaporizers without adding any diluting non-cannabis ingredients.

Non-Cannabis Ingredients

Propylene Glycol (PG), Vegetable Glycerin (VG) aka Glycerol, and Polyethylene Glycol (PEG)

Similar to what we are seeing in the commercial e-cigarette industry, some manufacturers of cannabis extract-containing vape pens choose to add ingredients that help adjust the viscosity of the cannabis oil. This allows the oil to flow evenly through the atomizer when heated. Some of these additives may also contribute to a vapor “cloud” when exhaled. PG, VG and PEG are the most commonly used cosolvents or diluents.

PG and VG are on the FDA’s Inactive Ingredient List¹⁸ for inhalable drug products and are allowable only at fairly low concentrations in drug products, but have been used at up to 90% concentration in e-cigarette products for the past decade without reports to date of significant health issues. PEG is not on the FDA’s list and less is known about its inhalation toxicity. Therefore, PEG should be viewed with more caution, even at lower concentrations.

The state of Colorado has paved the way for the industry on forward-thinking cannabis regulations and remains an industry leader. Governor Polis, his cannabis advisor, and the Marijuana Enforcement Division should be commended for creating an environment in the state that fosters business development while simultaneously protecting consumers. After discussions between Colorado regulators and stakeholders about additives, and given the lack of sufficient safety reviews of these ingredients, the state of Colorado prohibited Polyethylene glycol (PEG); Vitamin E Acetate; and Medium Chain Triglycerides (MCT Oil) in inhalable concentrates and products effective January 1, 2020.¹⁹ Colorado further banned non-botanical terpenes, any additive that is toxic, and any additive that makes the product more addictive, appealing to children, or misleading to patients or consumers.²⁰ Other states should consider following Colorado’s lead.

The creation of degradants through overheating is also an important consideration. For example, overheating PG and VG may result in their degradation²¹ into molecules with established toxicity profiles such as glyceraldehyde, lactaldehyde, dihydroxyacetone, hydroxyacetone, glycidol, acrolein, propanal, acetone, allyl alcohol, acetic acid, acetaldehyde, formic acid or formaldehyde. However, this degradation has been shown only with temperatures in excess of what is typically produced by well controlled hardware. Because PEG is a polymer of glycerin, its degradation upon heating is similar to that of VG and it forms the same unwanted toxic molecules.

Vitamin E Acetate and Tocopherols Inhalable Safety Profile Has Not Been Evaluated

Investigators at the FDA and CDC recently found that some cannabis-containing vape products from the illicit market contain a molecule called vitamin E acetate²² (VEA), also known as Tocopheryl acetate. Vitamin E is a common name for several similar types of chemicals called “tocopherols.” Vitamin E occurs naturally in certain foods, such as canola oil, olive oil and almonds, but also can be made synthetically. Tocopherols are used as nutritional supplements, and manufacturers put tocopherols in food and cosmetics. VEA is the acetic acid ester derived from vitamin E and is also not known to cause harm when ingested as a supplement or applied to the skin.

18. Inactive Ingredient Search for Approved Drug Products from U.S. Food & Drug Administration. Retrieved from: <https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>.

19. Colorado Marijuana Rules. 1 CCR 212-3. Section 3-335(L).

Retrieved from: <https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=8439&fileName=1%20CCR%20212-3>.

20. Id.

21. James C. Salamanca et al., *Formaldehyde Hemiacetal Sampling, Recovery, and Quantification from Electronic Cigarette Aerosols*, SCIENTIFIC REPORTS (Sept. 8, 2017), <https://www.nature.com/articles/s41598-017-11499-0>.

22. Lena H. Sun, *Contaminant found in marijuana vaping products linked to deadly lung illnesses, tests show*, WASHINGTON POST (Sept. 6, 2019), <https://www.washingtonpost.com/health/2019/09/05/contaminant-found-vaping-products-linked-deadly-lung-illnesses-state-federal-labsshow/>.

VEA's safety when inhaled has not been evaluated. Numerous published studies indicate that the inhalation of vaporized oils, including certain tocopherols, are harmful to the lungs and numerous cases of lung injury after their inhalation have been documented since 2000. Tocopherols such as VEA adhere to an important fluid in the lungs called lung surfactant. Lung surfactant enables oxygen to transfer from air into your body. Studies have shown that tocopherols impair gas transfer in the lungs. Currently it is believed that inhalation of significant amounts of certain tocopherols can lead to the death of lung cells and initiate a massive inflammatory reaction that can further contribute to lung damage and functional impairment. Accordingly, VEA should not be used as an additive in any inhaled product.²³ Following the FDA and CDC's investigation, Colorado added VEA to their list of prohibited ingredients in inhalables to their regulations effective January 1, 2020.²⁴

Artificial Flavorings Have Not Been Fully and Scientifically Evaluated.

Some manufactures of cannabis extract-containing vape pens choose to add flavoring agents to the cannabis oil to give them a distinctive flavor, similar to products in the electronic-cigarette industry. These additives tend to produce flavorings that are appealing to some consumers. While a number of flavorings have been used for many years without incident, the safety of the majority of flavorings when added to vaporized products - alone or in combination with cannabis extracts - have not been fully and scientifically evaluated.

In one study, certain chemicals that are used in flavorings for vanilla, cherry, citrus and cinnamon can create compounds called acetals when they are mixed with solvents such as PG and VG.²⁵ Acetals are known to cause irritation when inhaled and can lead to chronic inflammation in the lung. The long-term effects of these flavoring agents on lung function are unknown. A separate study showed that some popular flavorings may increase the risk of cardiovascular disease when inhaled, although several other studies show no negative effects.²⁶

As approximately 17 million Americans use vape products, many of which contain flavors, and only around 2,000 cases of e-cigarette, or vaping, product-use associated lung injury (EVALI) are currently being reported, it appears unlikely that all flavoring agents in all hardware devices are linked to EVALI. However, until more detailed safety studies have been completed on these product lines, manufacturers should proceed with caution.

Some Terpenes are Safe (GRAS); Some Can be Harmful When Heated

Terpenes are a class of molecules found in many plants, including cannabis, that are responsible for the aroma of the plant. Plants evolved to make terpenes to attract pollinators and to deter herbivores and unwanted pests. Terpenes are biologically active and help contribute to many of the physiological effects of inhaled cannabis. Isolated terpenes have been widely used as fragrances in perfumes in the cosmetic industry and in medicine, such as aromatherapy. Although many terpenes are considered "Generally Regarded As Safe" (GRAS) by the FDA, some terpenes are toxic when inhaled/ingested at high concentrations.²⁷ While most cannabis goods on the market contain levels of terpenes similar to those that occur naturally in the cannabis plant (~1-5%), some products contain terpenes at much higher concentrations (upwards of 25%). High levels of terpenes and other molecules can also occur if chemical procedures such as distillation are used to concentrate cannabis or hemp oil.

In general, terpenes are benign at low concentrations; however, overexposure to concentrated terpenes has the potential to lead to negative effects, including hypersensitive (allergic) reactions in chemically sensitive people.²⁸ Additionally, some vape pens do not have the means to adequately control the temperature and can heat the cannabis oil to a very high temperature. In certain instances, this has been shown to lead to thermal decomposition of some molecules in cannabis extracts, such as terpenes, resulting in the formation of new molecules with established toxicities.²⁹ It is also worth noting that even when these new molecules have been shown to form, they have been

FLAVORINGS



Vanilla



Cherry



Citrus



Cinnamon

23. *Electronic Cigarettes*, Centers for Disease Control and Prevention (last reviewed Jan. 3, 2020), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

24. Colorado Marijuana Rules. 1 CCR 212-3. Section 3-335(L). Retrieved from: <https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=8439&fileName=1%20CCR%20212-3>.

25. Hanno C. Erythropel, PhD, et al., *Formation of flavorant-propylene Glycol Adducts With Novel Toxicological Properties in Chemically Unstable E-Cigarette Liquids*, NICOTINE & TOBACCO RESEARCH (Oct. 18, 2019), <https://academic.oup.com/ntr/article-abstract/21/9/1248/5134068>.

26. Won Hee Lee, *Modeling Cardiovascular Risks of E-Cigarettes With Human-Induced Pluripotent Stem Cell-Derived Endothelial Cells*, JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY (June 2019), <http://www.onlinejacc.org/content/73/21/2722>.

27. Perry G. Fine, M.D., et al., *The Endocannabinoid System, Cannabinoids, and Pain*, RAMBAM MAIMONIDES MEDICAL JOURNAL (Oct. 2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3820295/>.

28. Rea WJ, et al., *Terpenes and Terpenoids in chemical Sensitivity*, PUBMED, (Aug. 2015), <https://www.ncbi.nlm.nih.gov/pubmed/26030111>.

29. Jiries Meehan-Atrash, et al., *Toxicant Formation in Dabbing: The Terpene Story*, AMERICAN CHEMICAL SOCIETY OMEGA (Sept. 22, 2017), <https://pubs.acs.org/doi/full/10.1021/acsomega.7b01130>.

detected in amounts that are lower in the vapor stream when compared to combustion and inhalation of plant products, such as cannabis flower, or tobacco leaf.

Cannabis-derived Terpenes

Cannabis contains terpenes, such that cannabis oil extracts used in vape products typically also contain these molecules, depending on the extraction method. Typically the distillation process causes a loss of terpenes. Some vape manufacturers now recover cannabis-derived terpenes during the distillation process and then re-introduce them back into the final formulated product. Because of poor process control, one potential safety concern from this procedure is that these cannabis-derived terpenes have an undefined molecular composition and the specific concentration of any terpene in the crude mixture likely varies from batch-to-batch due to numerous experimental variables. For example, many manufacturers that are producing large volumes of vape products by necessity must make the oil extracts from a mixture of cannabis strains. Since every cannabis strain contains different terpene profiles, this means that formulated products made from these strains will also vary in their terpene profiles from batch-to-batch.

The potential for terpene profiles changing during the manufacturing process could pose a potential safety concern. Additionally, new isomers, oxidative by-products or degradative terpenes may be present in these captured terpenes, which could possibly present hazards never presented by merely combusting and smoking the cannabis plant. Some states that have regulations on cannabis require analytical testing of formulated products, including the reporting of terpene concentrations, but this is not yet the universal standard. Vape manufacturers must exercise caution and be required to analyze terpene profiles of products they make in order to begin to develop a better understanding of this subject. Adhering closely to terpene concentrations known to be present in cannabis flower is a good practice.

Non-Cannabis Derived Terpenes Can Contain Residual Solvents and Pose Dangers

One widespread misconception in the cannabis vape industry is that cannabis-derived terpenes are somehow safer or better for you than non-cannabis derived terpenes. There are few cannabis-specific terpenes because most terpenes are also present in other plants. Most cannabis vape manufacturers

that operate at a large scale therefore prefer to use terpenes isolated from non-cannabis sources to introduce into their formulated products. There are several reasons why this is popular in the industry. High purity terpenes (e.g. >99% pure) are sold by numerous retailers, which allows these terpenes to be re-introduced into cannabis vape products at defined and safe concentrations. Also, the cost of using non-cannabis derived terpenes is far lower than the cost of isolating and using cannabis-derived terpenes.

For example, the terpene D-Limonene is present at extremely high levels in citrus fruits, and therefore can be isolated to high purity easily and inexpensively from them. In contrast, in most cannabis strains D-Limonene is only found at relatively low concentrations, and therefore one would have to use massive amounts of cannabis material to isolate significant quantities of this terpene required for companies that are operating at scale.

The origin and concentration of non-cannabis derived terpenes that manufacturers use in their formulations is nevertheless important. Non-cannabis derived terpenes from overseas often have several residual solvents in them, including ethanol, hexane, xylenes, benzene, butane and toluene. Moreover, some retailers of non-cannabis derived terpenes do not list the actual concentration or purity of terpenes in their products. It is imperative that cannabis vape manufacturers purchase and use non-cannabis derived terpenes that are accompanied by a COA that reports the purity of the terpene, any solvent(s) that may carry the terpene, and be required to adhere to the same purity standards and mandatory analytical testing requirements as cannabinoids. Reputable companies will also supply a safety data sheet (SDS) that describes the known toxicities of that terpene by different routes of ingestion, including inhalation.

Cannabis manufacturers that make formulated vape products should be aware of any toxic liabilities of non-cannabis derived molecules introduced into these products. Vape products should also undergo analytical testing for cannabinoids, terpenes and contaminants. Finally, analytical tests for aerosolized cannabis, similar to those used in the e-cigarette industry, should be developed, implemented and mandated to address safety concerns. The industry needs to build the volume of inhalation safety data required for all of these ingredients, hardware and end product combinations.

6. VAPORIZER DELIVERY DEVICES

Background

While technology used to vaporize cannabis extracts have been around for many years, advancements in vaporization technology and supply chains over the past decade have led to widespread adoption and growth of vaporization as a preferred method of cannabis consumption. Vaporizer devices offer the benefits of being discreet, allowing for metered consumption and eliminating carbon associated with combusting cannabis flower. However, not all vaporizer devices are created equal and manufacturers should develop an understanding of the nuances of different vaporizer devices to ensure delivery of a safe and high-quality experience. Aside from considering experiential qualities such as taste and the amount of vapor produced, manufacturers should consider at least the following three categories of issues that can present safety risks.


Physical Design Considerations

Vaporizer devices should be mechanically and electrically safe. This starts with relatively basic considerations that include ensuring the device is mechanically sound, does not leak alkaline or heavy metals, and is not configured in a manner that presents a safety hazard. In the early 2010s, there were many reported instances of vaporizer devices exploding. This was primarily due to improper electrical design and battery cell protection. Battery cells that are not protected from drawing current beyond their rated capacity or are allowed to drain too deeply present a safety risk. In fact, this risk led to the development of the UL 8139 standard for e-cigarette battery safety and the FDA recently relaxed its prohibition on e-cigarette battery changes in order to allow manufacturers to comply with this standard.³⁰ UL 8139 is applicable to vaporizer devices and anyone who sources or develops a vaporizer device for the cannabis market should voluntarily comply.

Contamination by Hardware

Vaporizer device hardware should be tested for the presence of heavy metals. Currently, some manufacturers use Restriction of Hazardous Substances (RoHS) testing or rely on vendor representations that the components and materials being used are certified as FDA food-grade. The California Bureau of Cannabis Control mandated heavy metals testing standards for the three categories of cannabis products, including inhalable cannabis products, starting on December 31, 2018.

Vaporizer device hardware that comes into contact with cannabis formulation should also be free of other contaminants. It is important to consider both contaminants that could be immediately detectable in vaporizer devices as well as those that can be released or created over time. Vaporizer devices are designed using a variety of industrial manufacturing processes, some of which can leave residual oils, biological agents or other substances in the device. It is important that device manufacturers clean incoming components, assemble them in a clean environment, then store and ship them in a manner that prevents re-contamination. Depending on the nature of the component, one or more of a cleaning bath or ozone treatment may be used for cleaning. After cleaning, assembly of vaporizer components should be performed in a clean room environment under appropriate current Good Manufacturing Practices (cGMP). Unfortunately, simply asking a



“...assembly of vaporizer components should be performed in a clean room environment under appropriate current Good Manufacturing Practices (cGMP). Unfortunately, simply asking a device manufacturer whether it operates in such a manner is not sufficient to be certain that it does.”

device manufacturer whether it operates in such a manner is not sufficient to be certain that it does. There is no substitute for first-hand inspection of manufacturing processes. While it may not be practical for U.S. based cannabis manufacturers to maintain a constant presence in the country of manufacture, it is possible to hire local agents who are skilled in audit practices and can perform unannounced inspections to verify that desired practices are implemented within the supply chain.

As noted above, hardware may also introduce contamination into the formulation over time, either through the process of leaching heavy metals or through chemical reaction. Leaching is a process whereby soluble constituents that may be present in materials dissolve into a formulation. A well-known example was the discovery that plasticizers present in certain plastic food and beverage containers were leaching and then being consumed.³¹ As a result, new types of plastics were developed

30 *FDA in Brief: FDA explains policy for manufacturers of battery-operated tobacco products and e-liquids who are considering making limited safety-related modifications to their products*, U.S. FOOD AND DRUG ADMINISTRATION (Nov. 25, 2019), <https://www.fda.gov/newsevents/fda-brief/fda-brief-fda-explains-policy-manufacturers-battery-operated-tobacco-products-and-e-liquids-who-are>.

31. MD Bethesda, *Report to the U.S. Consumer Product Safety Commission by the CHRONIC HAZARD ADVISORY PANEL ON PHTHALATES AND PHTHALATE ALTERNATIVES*, U.S. CONSUMER PRODUCT SAFETY COMMISSION (July 2014), [https://www.cpsc.gov/s3fs-public/CHAPREPORT-FINAL%20\(1\).pdf](https://www.cpsc.gov/s3fs-public/CHAPREPORT-FINAL%20(1).pdf).

for improved food safety. Vaporizer components that contact cannabis formulations may present a similar issue and leaching may be tied to metals, ceramics, plastics or other materials. In addition to leaching, certain materials may react with cannabis formulations, especially those with high terpene content which tend to be more volatile. Moreover, metal components in contact with formulations may be especially susceptible to leaching and lead to contaminants such as heavy metals in the formulation.

The good news is that it is possible to address this risk of leaching through the use of appropriate base materials and or plating. Base materials such as stainless steel are good candidates because of their low tendency to react with formulations. Plating other materials with corrosion resistant metals is also possible; however, care must be taken to specify the right material and plating thickness while also ensuring the plating is not damaged during assembly.

With proper material selection and design, it is possible to reduce the risk of such contamination, including through conducting stability tests. In a stability test, a formulation is placed into the vaporizer device for a period of time, then removed and tested for contaminants. A good guide is to design the stability test to align with the desired shelf life of the product. That doesn't necessarily mean the test needs to be as long as the rated shelf life. Typically, elevated temperature tests are used to determine stability and can cut the duration of the test to 50% or less of the desired shelf life. In addition, by taking measurements at intermediate intervals, stability can be better characterized and the point at which contaminants would exceed their respective limits can be projected.

Device Impact on Formulation: Control the Heat

The most fundamental, yet perhaps the most underappreciated aspect of vaporizer devices is how they vaporize cannabis formulations. Setting aside dry herb vaporizers, all liquid cannabis vaporizers basically work by bringing the formulation into contact with a hot surface in order to heat it and thus create vapor. While this may seem straightforward, there are a number of subtleties that affect the outcome. First, the temperature of the hot surface must be hot enough to heat the liquid, yet not so hot as to cause components of the formulation to degrade into byproducts that could be harmful. In fact, one study demonstrated how changing the voltage, and thus the temperature of an

unregulated vaporizer device can affect the production of such degradants.³² While more advanced vaporizer devices attempt to control vaporization temperature by using heating elements made of specific materials that indirectly measure temperature and regulate the power delivered to the heating element, the majority do not.

Different formulations have different compositions and contain constituents that vaporize and degrade at various temperatures. This means that to fully control vaporization, the vaporizer device must be configured precisely to the requirements of the formulation in use. Second, many vaporizer devices do not heat uniformly. Rather, the heated surfaces heat unevenly, creating hot spots that can locally trigger thermal degradation. Temperature control circuits typically measure an average temperature and do not prevent such hot spots. Finally, the majority of vaporizer devices, whether they contain fiber wicks or ceramic, rely on capillary action to bring the formulation into contact with the heated area or surface. During a puff, capillary action is also what replenishes the formulation at the heated surface, and such capillary replenishment takes time. Depending on the viscosity of the formulation and the duration of the puff, a heated surface that was initially saturated with formulation can become dry and hot during the course of a puff. Experienced users sometimes refer to this as a "dry hit," which can be perceived when a cartridge runs dry or during a long puff. Dry hits can result in increased thermal degradation.

Armed with this understanding of the nuances of vaporizer devices, one can appreciate how the common business model of selling cartridges with a universal 510 threaded connection that can be used in conjunction with any number of batteries, any number of power settings, and filled with a variety of formulations makes it difficult to guarantee what is produced during vaporization. In order to understand and control the output of a vaporizer device, the system should be designed, configured and tested as a whole; cartridge and battery, plus formulation. Closed systems with proprietary connectors and one-piece designs do not face the cartridge-battery mismatch challenge, but should still be tested in conjunction with the target formulation using a reasonable worst-case puff duration. And while new systems under development that employ non-contact heating methods may not present the same temperature control challenges, they too should be validated as a whole.

32. James C. Salamanca, et al., *Formaldehyde Hemiacetal Sampling, Recovery, and Quantification from Electronic Cigarette Aerosols*, SCIENTIFIC REPORTS (Sept. 8, 2017), <https://www.nature.com/articles/s41598-017-11499-0>.

7. POSSIBLE CONTAMINANTS AND TESTING

State-Mandated Testing Programs are Essential to Protecting Consumers

Reliable vaping products manufactured using suitable vaporizer hardware and liquid formulations created from high quality ingredients are common in the legal cannabis market. However, if the settings on the hardware are not appropriate or if low-grade ingredients with impurities are used, vaping products may contain contaminants or produce harmful byproducts during the act of vaporization. We can assess the quality and safety of products by performing testing in a certified laboratory.

Currently, most states that have a legal cannabis market have implemented a mandated testing program to protect public safety. Current programs can include:

- **Potency and terpene testing to determine if the label claim of THC, CBD, and other cannabinoids, and terpenes is accurate within a permitted variance;**
- **Residual solvent, pesticide, and heavy metal testing to ensure that products do not have harmful levels of chemicals in the final products; and**
- **Microbial testing to confirm that yeast and mold, if any present, are at safe levels and that products do not contain pathogenic fungi or bacteria that are injurious to human health.**

In states with mandated testing programs, all or some of the tests mentioned above are performed on final liquid formulations going into vape pens or cartridges. For edibles that are orally consumed or topicals that are applied to one's skin, there is little risk for major chemical changes or byproducts produced during the act of consumption. Therefore, testing just the final products in this case may be appropriate to assess quality and safety.

However, when one consumes a liquid formulation in a vape pen or vape cartridge, the process of vaporization has a higher risk of inducing harmful chemical changes. Liquid formulation testing may not provide enough information to fully assess safety in these products. Testing the vapor that is produced can provide more probative information on what is actually consumed. Some cannabis manufacturers are engaging in research that focuses on vape emissions.³³

Emissions Testing Should be Regular Practice

A key principle in making sure that products are safe for human consumption is to test the product in the form in which it is consumed. In the case of vapor products, that means testing the vapor. Indeed, testing emissions is now standard practice in the nicotine e-cigarette market. It is required in Europe by the Tobacco Product Directive (2014/40/EU) and is part of the FDA's guidance for premarket product approval. While some differences in testing cannabis vapor products may be appropriate, the fundamental approach provided by these two regulatory frameworks is sound. Though no states currently require emissions testing of cannabis vapor products, it is likely that states will look to these models and implement similar requirements. Moreover, emissions testing should be considered part of a good safety program and used to mitigate against unanticipated risks.

Various methods exist for conducting emissions tests. The basic principle is to connect the vapor device to a machine that simulates inhalation, collect what is inhaled and analyze the collected material using standard lab methods. Sometimes it is necessary to use more than one method to collect the emissions. Figures 1 and 2 below show two of the more common

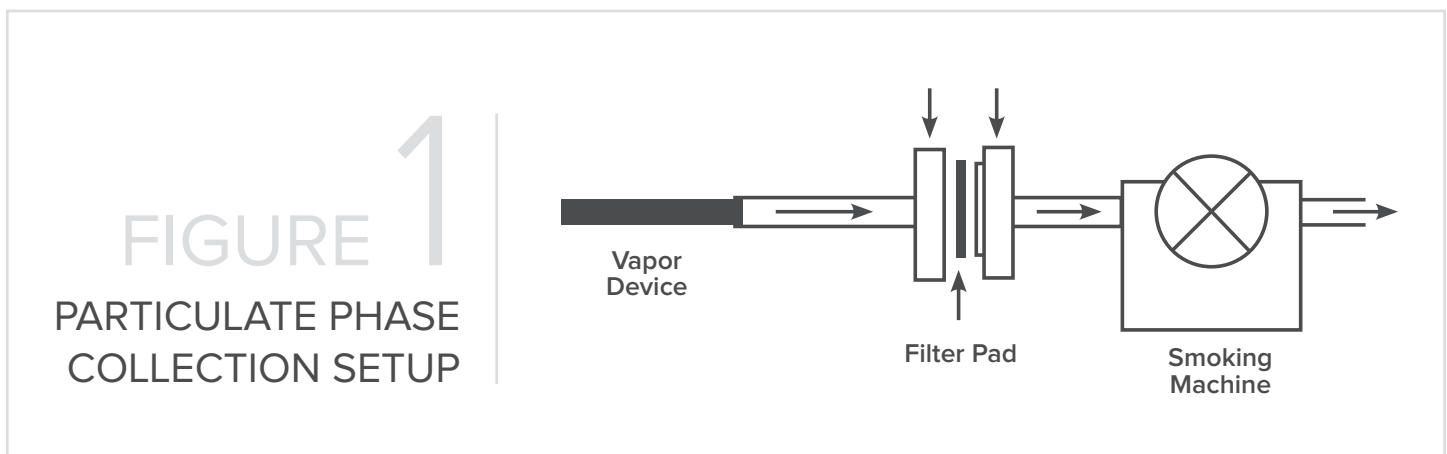
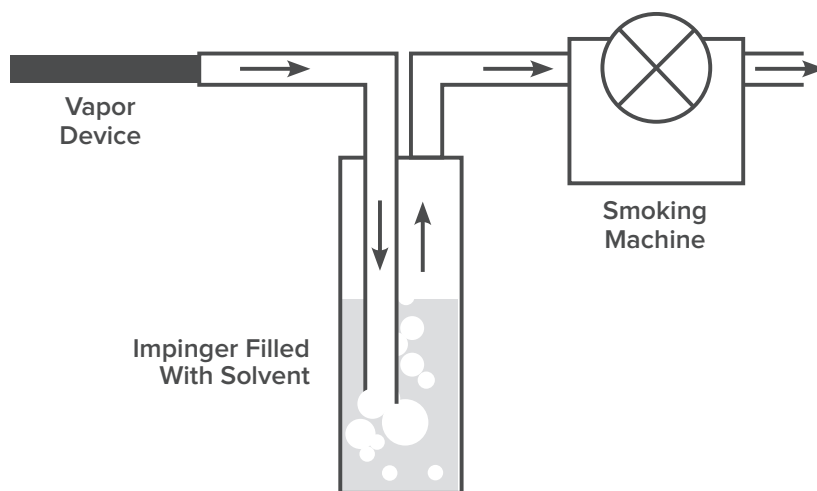


FIGURE 1
PARTICULATE PHASE
COLLECTION SETUP

33. *The Blinc Group and Think20 Labs Announce Research Partnership Focused on Cannabis Vaping Emissions*, PR NEWswire (Oct. 3, 2019, 5:47 PM), <https://www.prnewswire.com/news-releases/the-blinc-group-and-think20-labs-announce-research-partnership-focused-on-cannabisvaping-emissions-300931004.html>.

FIGURE 2 GAS PHASE COLLECTION SETUP



setups. Figure 1 is commonly used to capture particulate matter from the vapor stream. In this setup, a special type of filter such as a Cambridge filter pad is placed inline between the vapor device and the inhalation generator, otherwise known as a smoking machine. After collection, the particulate matter is then extracted from the Cambridge filter pad using a solvent. A second type of setup, shown in Figure 2, is used to collect gas phase emissions. In this setup, a double impinger containing a special solvent is placed in-line between the vapor device and the smoking machine.

In addition to understanding the physical setup, inhalation parameters must be considered. Smoking machines can be programmed to simulate a variety of inhalation profiles. In nicotine e-cigarette testing, it is common to test using a 3-second-long inhalation with a volume of 55ml and a 30 second interval between puffs; this mimics a typical smoker's behavior. This method, which may inform cannabis vapor product testing, is more fully detailed in the Cooperation Centre for Scientific Research Relative to Tobacco's Recommended Method #81.³⁴ A different inhalation profile, perhaps longer inhalations and longer intervals, may be appropriate for cannabis products. But, it is important to simulate real-world use to understand the emissions produced by vapor products. For example, in some devices, short inhalations with long intervals tend to result in lower vaporization temperatures and thus lower problematic emissions. Long inhalations with short intervals may lead to excessive temperatures and dry regions in wicks and porous ceramics, which can lead to higher levels of unwanted emissions.

Furthermore, it is important to note that overall emissions depend not just on the formulation and cartridge design, but also battery design and settings. For example, it has been shown that systems without good temperature control can produce higher emissions at higher power settings.³⁵ This highlights the importance of testing systems as a whole. For sellers of cartridges that do not also sell accompanying batteries, it would be impractical to test their cartridges with all possible batteries. However, it is possible to test with a recommended battery at the appropriate settings and inform consumers of this recommendation.

Once sample collection has been performed using the previously described setups and appropriate profiles, the resulting solution containing the captured emissions may then be analyzed using standard techniques such as High Performance Liquid Chromatography (HPLC). At a minimum, the collected emissions should be analyzed for potentially harmful constituents. A comprehensive list of such constituents has not yet been developed for cannabis vapor products; however, select analytes from California's phase III testing requirements³⁶ and FDA's Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems draft guidance document³⁷ provide a starting point. Cannabis researchers, operators and industry associations should work together to catalog yet to be identified cannabis-vapor-specific degradant molecules in order to develop an agreed upon list of vapor analytes that may be shared with manufacturers and regulators.

34. *Routine Analytical Machine for E-Cigarette Aerosol Generation and Collection - Definitions and Standard Conditions*, Coresta Recommended Method N 81 (June 2015), https://www.coresta.org/sites/default/files/technical_documents/main/CRM_81.pdf.

35. Jiries Meehan-Atrash, et al., *Aerosol Gas-Phase Components from Cannabis E-Cigarettes and Dabbing: Mechanistic Insight and Quantitative Risk Analysis*, ACS OMEGA (Oct. 1, 2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6777088/>.

36. Cal. Code Regs. tit. 16 §§ 5000 et seq.

Retrieved from: <https://cannabis.ca.gov/wp-content/uploads/sites/13/2019/01/Order-of-Adoption-Clean-Version-of-Text.pdf>.

37. *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems Guidance for Industry*, FOOD AND DRUG ADMINISTRATION CENTER FOR TOBACCO PRODUCTS (June 2019), <https://www.fda.gov/media/127853/download>.

Most cannabis manufacturers do not currently have the equipment or expertise to perform emissions testing. It is therefore incumbent on manufacturers to either develop such expertise or establish relationships with labs that can perform this type of work. To date, only a few accredited cannabis testing laboratories are known to have such capabilities. More are expected to follow suit. Indeed, manufacturers can also invest in bringing emissions testing capabilities in-house for quality assurance and quality control of final products. This can not only be useful for predicting the outcome of mandated final testing by licensed independent third party labs, but also for product development as it gives real time insight into how changes in formulation, hardware and settings influence emissions. Those companies looking to build such capabilities would need to invest in a few basic pieces of equipment including a smoking machine, a Gas Chromatography Mass Spectrometry (GCMS) machine and HPLC machine. Simple smoking machines can be procured for a few thousand dollars, while more full-featured machines can run in the low tens of thousands. While new GCMS and HPLC machines can cost approximately \$100K each, they are already important tools in cannabis product analysis and can be put to use in a variety of testing applications for numerous products. A note of caution when building in-house expertise; good equipment does not guarantee testing validity as test results are only as good as the methods. Considerable attention must be put toward validating vapor collection and analysis methods.

Supply Chain Verification Through Better Record Keeping

To improve the quality of the supply chain supporting medical and adult-use outlets providing vapor products, consideration should be given to requiring protocols for recording all ingredients and sub-components of such products with origin transparency back to an insured party. This record should be maintained by the brand's licensed Original Engineering Manufacturer (OEM) of final branded product in its government approved Enterprise Resource Planning (ERP) or approved tracking system.


Vendors and brands should be held accountable for the products they produce. This includes, but is not limited to raw materials, excipients and delivery hardware that ultimately comprise the final product. This record should be made available to appropriate governing bodies within jurisdictional oversight. The primary purpose of record keeping to such a granular level allows both companies and officials to work together to identify issues early and reduce the spread of a potential issue found in a regulated market. For example, regulated record keeping would have been useful in the recent outbreak of EVALI. Of course, traceability only works in the regulated market.

Problems associated with the introduction of excipients such as vitamin E acetate may have been caught in early testing with the methods discussed above. An increase in record keeping would allow for cleaner audit protocols between companies and officials. Once an issue such as EVALI is discovered, officials would have another tool in their chest to help identify inconsistencies in the products in question. Such records could also be connected to additional data sets such as lab results of the tests mentioned above to help verify or deny the validity of a given product.

Counterfeit products from the illicit and unregulated market are large contributors to supply chain problems that endanger public safety. Two

studies performed by CannaSafe, showed test results of purchased product from both regulated and unregulated/illicit markets. Only the illicit products showed unacceptable levels of contaminants, such as heavy metals, pesticides and varying levels of vitamin E acetate.^{38, 39}

In summary, the Policy Council recommends the following supply chain improvements. First, we must enable government transparency to ERP gateways by mandating that vendors and brands add additional information into state mandated inventory tracking systems. Second, all ingredients and subcomponents should be recorded, so they can be traced back to each insured party in ERP (above and beyond general "seed-to-sale" tracking required to satisfy state regulations). And third, labeling requirements should be implemented for final packaging to follow end products.



***“Vendors
and brands
should be held
accountable
for the
products they
produce.”***

38. *Vitamin E Report*, CANNASAFE (Oct. 2, 2019), https://csalabs.com/wp-content/uploads/2019/10/CannaSafe_VitaminEAcetate_Report.pdf.

39. *Vapes Report: What Are You Actually Inhaling?*, CANNASAFE (Nov. 13, 2019), https://csalabs.com/wp-content/uploads/2019/11/CannaSafe_VapeReport.pdf.

8. RECALLS IN A REGULATED MARKET

One key post-production safety benefit of the regulated vaporizer market is the ability to recall products in the unlikely event of a subsequently discovered potential safety issue. The value of effective recall procedures extends far beyond cannabis; recall procedures are an essential ex post safety procedure for any consumer good.

This important safety mechanism is already present in states with regulated cannabis markets, which often have explicit regulations requiring recall procedures. For example, these regulations cover important steps such as notification to supply chain partners, to the public and to regulators, as well as a quarantine for regulatory audit.⁴⁰ These regulatory requirements can also address not only voluntary recalls initiated by licensees, but also recalls initiated by regulators.

Both regulator-mandated and voluntary recalls highlight a further key safety mechanism available to the regulated market. Regulator-mandated recalls definitionally cannot exist in the illicit market. After all, there is no regulator to set standards for an illicit market or impose punitive measures against those who violate them. But the conditions of the illicit market also pose significant challenges to any public health-minded illicit market operators who would like to initiate public safety “recalls.” First,

there is an informational deficit compared to a regulated market. These products are not flowing through qualified third-party labs to red flag products, and consumers who are sickened by these products are likely to be reticent to raise their concerns with their illicit market supplier or to provide information to public health officials. Second, it is reasonable to assume that there is a fragmented, atypical supply chain in the illicit market. For example, participants in the illicit market are unlikely to have contracts allocating risk for defective products, and participants will not be able to turn to the courts to adjudicate the proper allocation of such risk. Wherever a safety risk is discovered in the illicit market supply chain, that individual will likely be faced with a choice between selling dangerous products or losing their entire financial investment in those products. As a result, tainted products in the illicit market are more likely to be sold to consumers, even if such a risk is identified. The good news is that a regulated market for cannabis—like other regulated markets for human consumables—is far less likely to include products that pose an unexpected danger to human health than an illicit market. But as with the market for other consumable products, the ability for the industry or regulators to identify products for recall provides an important safety benefit to the public.

9. MARKETING TO CHILDREN AND TEENAGERS

NCIA’s Policy Council recently published a white paper on “Cannabis Packaging and Labeling: Recommendations for Sensible and Consistent Regulations Across States and Nations.”⁴¹ All of the goals in that white paper are compatible with the recommendations presented here. We urge policy makers to heed the message of our paper and incorporate restrictions on marketing to minors into all regulatory frameworks.

Recommendation #18 of the white paper suggests prohibiting packaging that is attractive to minors, including packaging that depicts a minor or portrays objects, images or cartoon figures that primarily appeal to minors. Packaging is considered to

“primarily appeal” to minors if it has special attractiveness to minors beyond the general attractiveness it has for persons of legal purchase age. The Policy Council believes that the overwhelming majority of cannabis businesses share this goal, and that regulation is the best way to keep cannabis away from children. The Policy Council also found that the voluntary Code of Responsible Practices of the Distilled Spirits Council of the United States (DISCUS)⁴² and Oregon’s current cannabis regulations provide excellent models, which were both drawn from Model Regulations.⁴³

40. Cal. Code Regs. tit. 17, § 40297.

41. NCIA’s Policy Council, *Cannabis Packaging and Labeling: Recommendations for Sensible and Consistent Regulations Across States and Nations*, NATIONAL CANNABIS INDUSTRY ASSOCIATION (Feb. 2019), <https://thecannabisindustry.org/reports/cannabis-packaging-and-labeling-recommendations-for-sensible-and-consistent-regulations-across-states-and-nations-february-2019>.

42. Distilled Spirits Council of the United States. Code of Responsible Practices, pg. 5. 2011. Retrieved from: https://www.distilledspirits.org/wpcontent/uploads/2018/03/May_26_2011_DISCUS_Code_Word_Version1.pdf.

43. OAR 845-025-7020(3)(c) and 845-025-7000(1).

10. STATE GOVERNMENT ACTIONS

In response to EVALI and recommendations by the CDC and FDA, several states with medical and adult use cannabis regulations have acted to address THC infused vaping products, up to partial or complete bans on the manufacture, distribution and sale of vaping products. Beginning in September 2019, several states issued temporary bans on all flavored vaping products, including flavored THC vaping products. This included states such as Massachusetts, Michigan, New York, Oregon and Washington. Some of these temporary bans have been overturned by the courts, however, including in Massachusetts, Michigan and New York. Many states that have not yet implemented a ban on flavored vaping products will discuss the topic during their respective 2020 legislative sessions. Most current proposals, however, are targeted

primarily toward flavored nicotine vaping products. The majority of state proposals do not extend proposed flavor bans to regulated cannabis products that undergo rigorous testing, particularly now that a strong scientific consensus has emerged that the underlying cause of EVALI arises from unregulated additives in illicit market vaping products. Instead, many states such as Colorado, Maryland, Ohio and others are implementing new regulations that prohibit specific ingredients in cannabis vaping products, including polyethylene glycol, vitamin E acetate and medium chain triglycerides. Other precautions under consideration in many states include more robust label requirements and product warnings. Other states should follow suit and make sure that potentially dangerous additives are not added to cannabis oil.

11. CONCLUSION

The cannabis industry has a serious and disruptive illicit market problem that is directly affecting public health and safety. While the Center for Disease Control has not yet definitively determined the proximate cause for every injury or death, the overwhelming preponderance of the evidence points to additives in illicit market products. NCIA's Policy Council urges consumers to only purchase regulated and tested cannabis products from the state-legal market. Reliable vaping products manufactured using suitable vaporizer hardware and liquid formulations created from high quality ingredients are common in the legal cannabis market. The same cannot be said for the unregulated market. We must stop the flow of illicit, unregulated, and untested products to consumers. That is the ultimate solution to the vaping crisis. We also need to lower taxes, so that the legal market can fairly compete with the illicit market. This effort will take a collaborative approach, with law enforcement, state-legal cannabis businesses, and state cannabis taxing and licensing authorities working in concert.

As the Center for Disease Control continues to investigate the proximate cause of lung injuries and deaths, it is incumbent upon the industry to do all that we can to keep consumers safe. This includes educating and encouraging consumers to: (1) purchase cannabis products from the state-regulated market at a licensed dispensary, (2) consume cannabis oil without additives (live resin), (3) purchase devices and batteries from reputable manufacturers that take precautions in the manufacturing of such products, (4) refrain from purchasing products on the illicit

market (whether from retail stores, illicit street dealers, or online), and (5) take care to make sure that cannabis products have been tested by a licensed and accredited laboratory.

The American consumer clearly wants cannabis products to be both accessible and legal. It's time for the federal government to deschedule marijuana and regulate it like alcohol. Legalization through descheduling, regulation and testing is the best path forward to keeping consumers safe. In the end, sensible regulation and a clear path to licensure and compliance will be the most compelling force in driving people from the illicit market to the state-legal market.



To learn more about the Policy Council and our work to protect the state-legal cannabis industry, please contact

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