MPP Policy Paper

Regulating Cannabis Oil Vaporizers

I. Overview

A series of pulmonary illnesses and fatalities are being attributed to nicotine and cannabis vapor products. Although the products responsible for these medical emergencies are widely believed to have come from the underground, unregulated market,[1,2] these illnesses raise serious issues that can inform regulated medical cannabis and adult-use programs.[3]

This paper discusses some of the underlying issues and makes specific recommendations to state lawmakers and regulators on best responses. **Regulating cannabis use is effective public policy, and we strongly urge states to regulate — not ban — vapor products.** Bans will simply make a difficult situation more dangerous by driving more consumers away from regulated businesses and toward illicit sources. Moreover, such a policy also fails to address the underlying problem of contamination. We believe the right approach was initiated in Pennsylvania, where state regulators

[1] Centers for Disease Control and Prevention, "Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping," September 19, 2019, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.
[2] Rob Kuznia, "Potential culprits in mystery lung illnesses: Black-market vaping products," *The Washington Post*, September 25, 2019, https://www.washingtonpost.com/health/potential-culprits-in-mystery-lung-illnesses-black-market-vaping-products/2019/09/24/cb5b708e-d98d-11e9-ac63-3016711543fe_story.html; Jessica Bursztynsky, "Ex-FDA chief Gottlieb blames outbreak of deadly vaping illness on illegal nicotine products," *CNBC*, September 25, 2019, https://www.cnbc.com/2019/09/25/ex-fda-chief-gottlieb-blames-outbreak-of-deadly-vaping-illness-on-illegal-nicotine-products.html.
[3] While indications are the source of the products was the unregulated underground, licensed companies are possible targets in broad products liabilities legal actions, such as that filed in Washington, *Charles Wilcoxson v. Canna Brand Solutions LLC et al.*, filed on September 23, 2019, in the Superior Court of Pierce County.

recognize that regulated products are the solution — not the problem.[4] Yet, more can be done, and we explore that here.

II. Background

Policymakers considering policies related to vaporizers should keep in mind several things related to this discussion:

- **The cause is not yet clear, but widely believed to be an additive.** While vaporizer technology has been in use for over 10 years, illnesses that are now reported began in April 2019.[5] All indications are that it is not cannabis itself or any concentrated form of cannabis leading to these medical emergencies. Early indications suggested a particular additive, Vitamin E acetate, might be the culprit, but that conclusion is uncertain.[6] So far, researchers have not identified the cause, and additional research is taking place to try to identify additives and contaminants causing illness. Additionally, symptoms have occurred over a large geographic area and across a wide range of products, including both nicotine-only and THC-only products.[7]

- **Vaping is particularly important for patients — and many others.** For those who are health conscious, vaping cannabis products is an effective and popular option compared with smoking cannabis. This can be the case particularly for those who rely on the quick onset of cannabis' therapeutic effect, such as pain patients. Some jurisdictions have even banned cannabis smoking with the expectation that vaping will be an effective alternative.[8] Vape pens have been available for more than a decade without known acute health concerns and are a favored means of administration in nearly every comprehensive cannabis program, whether medical or adult use.

[4] Secretary of Health Dr. Rachel Levine noted, among other observations, that "Pennsylvania's medical marijuana program is carefully regulated, with products going through extensive laboratory testing." https://www.media.pa.gov/Pages/Health-Details.aspx?newsid=651 Rather than prohibiting sales, regulators want consumers to limit use to products coming from its regulated system.

[5] Hannah Knowles and Lena H. Sun, "What we know about the mysterious vaping-linked illness and deaths," *The Washington Post*, September 17, 2019, https://www.washingtonpost.com/health/2019/09/07/what-we-know-about-mysterious-vaping-linked-illnesses-deaths/.

[6] *Id*.

[7] *Id*.

[8] Illinois' new legalization law prohibits smoking cannabis, but allows vaporized cannabis products. Georgia's medical cannabis program prohibits all forms of ingestion except cannabis oil vaporizing. Similarly, New York's medical program also allows vaporizing but forbids smoking.

- **This issue relates to a particular kind of vaporizer product.** The type of vaporizer product at issue is often referred to as a "vape pen."[9] These are hand-held devices that heat a liquid solution to a sufficient temperature so that it can be inhaled as a gas or aerosol. The liquid is housed within a cartridge designed for use with the particular vape pen and might contain THC, CBD, or other constituents from the cannabis plant. This cannabis-based vaporizer liquid is often referred to as "cannabis oil." Alternatively, vape pens can contain nicotine products derived from tobacco (which are more commonly referred to as electronic cigarettes or " e-cigs"). For the purposes of this paper, our discussion is limited to cannabis-derived vaporizers, although both are implicated in the recent health concerns.

- **The cause is believed to be related to the production process.** It is the process of creating the vaporizable liquid concentrate that is now under scrutiny. To make the contents of vape cartridges, the active ingredients in the cannabis plant are first extracted, refined, and placed in a liquid medium that is suitable for vaporizing. Cannabis oil allows for a consistent product containing a measured amount of active ingredients. Cannabis oil may also include other ingredients to make the cannabis oil capable of vaporization, or to serve as a preservative, or to even lower levels of THC to conform to state potency limits. Investigators believe, but have not yet confirmed, that one or more of the additives used in the underground manufacturing process has led to a toxic product when inhaled.

- **Not all vaporizers are under scrutiny.** There are different types of cannabis vaporizers and not all use the same technology. Some vaporizers, often called herbal vaporizers, heat the raw plant material itself, rather than cannabis oil derived from the plant matter, to produce an inhalable product. While some states have taken the unfortunate step of banning a wide range of vaporizer products, the specific health concerns are limited to cannabis oil vaporizers.[10]

- **Federal regulators are a no-show.** While important federal standards apply to the manufacture of vape pen and e-cig devices, regulation of the cannabis oil used in vape pen cartridges is not yet available at the federal level. Instead, states must adopt their own standards, creating a patchwork system.

- **Banning a popular product is a bad idea.** Vaporizer products are popular and easy to produce, and vape pens now represent an estimated 23.8% of the adult-use cannabis market. Sales for medical cannabis patients are often far greater.[11] Banning cannabis

[9] Devices may also be referred to as vaporizers, vapes, e-cigarettes, e-cigs, and others. Note that among some groups, "e-cig" denotes a vape pen used for nicotine solutions rather than THC, but terms vary widely.
[10] Not only are bans of *regulated* products an ineffective response to dangerous *underground* products, but also they can be overbroad, as in the case of Maryland's decision impacting more products than have been implicated.
[11] Mel Hyman, "Vaping ailments put damper on cannabis rise," *New York Post*, September 22, 2019, https://nypost.com/2019/09/22/vaping-ailments-put-damper-on-cannabis-rise/.

oil-based vaporizer products will fail to address the (likely) underlying problem of harmful additives, and it will also drive more consumers to the underground market where cartridges and their sales are unregulated. Adults should have access to safe products, and they should be encouraged to avoid illicit dealers.

- **Unrelated vaping issues are easily conflated.** A familiar news story relates to concerns over teen use of nicotine products, and most notably, flavored vaping products. By contrast, the recent health concerns relate to the underground manufacture of unsafe products for adult consumers. Both are serious but are very different concerns, and it is likely they have different solutions.

III. Regulatory Control Today

There are several ways regulatory systems can address issues related to product safety. MPP recommends that every state regulatory system include the following:

1. **Product testing.** States should require cannabis products to be tested for the presence of harmful contaminants or the detection of prohibited ingredients. Testing should be performed after the cultivation process and a second time if there has been further post-cultivation processing of raw cannabis into other products such as edibles, topicals, or here, oils intended for vaporization. Agencies should receive notice of failed tests directly from the testing labs, and results should be available for a number of years.
2. **Manufacturing standards.** While product safety is a role usually taken by the FDA, that agency's inability to regulate most cannabis products has placed a significant burden on state regulators. Following product testing itself, establishing and enforcing manufacturing standards is the primary means of regulatory control over the safety of cannabis products. These should include:
    a. Facility and equipment standards and maintenance standards;
    b. Operational standards related to the extraction and infusion process, including solvents and other chemicals used and techniques employed;
    c. Quality control standards to ensure consistent products that are free from defects;
    d. Worker training requirements covering the extraction techniques used and chemicals employed; and

e. A clear list of allowable (or prohibited) solvents used for extracting active ingredients from plant material.

3. **Labeling standards.** Regulatory authorities should have the ability to add or change product label requirements whenever needed, particularly when related to health and safety.

4. **Broad rule making authority.** Agencies should have the ability to make rules without turning to lawmakers for authority to act — again, particularly in areas addressing health and safety.

5. **Agency action.** Regulators should have the ability to directly respond when particular product safety concerns arise. Actions could include suspending, revoking, or refusing to renew business licenses from violators or seeking administrative or judicial relief, including injunctions. Agencies should also be able to order product recalls, issue bulletins to the public or other businesses about health and safety concerns, and issue substantive fines.

6. **Prohibiting hazardous ingredients.** States should include a blanket ban on harmful and potentially harmful constituents, including allowable levels in trace amounts. Such a provision may be of assistance if rules are otherwise not clearly applicable to a product safety question and agencies need authority to act quickly. As discussed more fully below, the state should also develop a list of approved or prohibited additives, particularly for inhaled products.

IV. Additional Regulatory Controls

All indications suggest the products that led to the recent health threat did not originate from within a regulated state program, but they do raise questions about vaporized cannabis oil products. Some policymakers might wish to take steps beyond those that are part of regulatory systems today.

While many questions remain in the investigation, some reasonable steps are certainly available and others can be anticipated. In addition to the regulatory controls outlined above, MPP suggests that regulators and policymakers in adult-use and medical cannabis states consider the following:

Short term: Educate consumers

1. **Content labeling.** While labels commonly provide the amount of active ingredients (and in particular THC and CBD), not all states require inactive ingredients, including additives. Labels should include all ingredients.

2. **Chain of custody.** Consumers should be able to learn the provenance of a particular regulated cannabis product, including verification that the product came from one or more licensed businesses.

3. **Warn consumers about unregulated products.** Make sure consumers understand the difference between licensed and unlicensed cannabis products, particularly those involving post-cultivation processing, and ensure the state program doesn't inadvertently push consumers to the underground, such as through overly burdensome taxes. One of the biggest reasons for the regulation of cannabis businesses is to help foster the health and safety of consumers. Adults or patients who purchase outside these regulated programs can face serious risks and should be warned.

Medium term: Control additives

1. **Ban additives considered harmful.** While the exact cause is unknown, researchers generally believe harmful additives may be the source of the problem. If so, any additives deemed harmful should be banned.

2. **Develop a list of harmful and potentially harmful constituents.** While states often require or ban specific solvents in the extraction process, most states do not currently list chemicals that are prohibited as additives. Some of this work has been done by the FDA with respect to e-cigarettes, but more work related to cannabis products needs to be done.

3. **Adapt testing.** Once we understand better what chemicals or combination of chemicals led to the recent illnesses, regulators should revisit their testing requirements and include them in the testing screen.

4. **Test what is consumed.** State testing should include testing of the cannabis oil in liquid form, but states should also consider testing it in aerosol form — the form in which it is introduced to the body.

Long term: Replace national cannabis prohibition with regulation

The safety of products intended for human consumption typically falls under the jurisdiction of the FDA, and some cannabis products — particularly those made with hemp — are now subject to FDA oversight. But the federal government's refusal to remove non-hemp cannabis from the Controlled Substances Act and legalize it for adult use has resulted in a system in which millions of Americans have access to cannabis products without the oversight many of us expect. This places a greater burden on consumers who should be informed about the products they use, and state regulators who must include health and safety criteria in their regulatory systems.

The federal government should not be allowed to sideline itself from this discussion because of its outdated and unpopular anti-cannabis drug war policy. The FDA's mandate is the health and safety of products consumed by Americans, and the fact that federal regulators are not involved should no longer be acceptable. This lack of involvement reaches many areas in cannabis policy, including taxes, banking, lab testing and labeling, transport, and many others.

States must continue to encourage their representatives in Congress to develop a framework for cannabis regulatory control, including regulations that can help ensure the health and safety of products that would be applied across all jurisdictions.

Conclusion

The recent incidents involving cannabis oil vaporizers are serious, and while current investigations do not indicate they came from a regulated medical or adult-use cannabis program, they do raise questions about ensuring product safety. We believe more can be done.

Regulators should help consumers get information they can use, such as a complete ingredients list for cannabis products and the ability to verify the source of the product. Consumers should also understand that unregulated products can carry risks.

Regulators should also revisit testing standards and their list of prohibited and permissible additives. Regulations should include not only solvents for extracting active ingredients, but also additives that may be introduced in the production process for cannabis oil.

Ultimately, the federal government should be part of the conversation, with a comprehensive approach to product safety testing that can come with legalization at the federal level. State lawmakers should continue to press Congress to end cannabis prohibition.