



Health Benefits and Risks of Cannabis Vaporizers and Vape Pens

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INTRODUCTION

California NORML has long recommended cannabis vaporization over smoking for users who wish to reduce their exposure to harmful smoke toxins, based on scientific studies that have shown that vaporization, when properly done, drastically reduces exposure to harmful smoke toxins. However, the recent outbreak of EVALI disease among users of certain THC and CBD vape pens raises concerns about the hazards of contaminated and defective products, and the need for more careful regulation of cannabis vape extracts and cartridges.

WHAT IS VAPORIZATION?

The principle of cannabis vaporization is simple. When marijuana is combusted in a cigarette or pipe, the burning leaf produces a smoke-stream of noxious particulates, gases, and tars, such as benzene, acrolein, carbon monoxide, formaldehyde, cyanide, nitrosamines, and a host of carcinogenic polycyclic aromatic hydrocarbons. These toxins do not come from the active ingredients in the plant: the cannabinoids and terpenes. Rather they are byproducts of the combustion of cellulose, amino acids, and other inactive plant components, which constitute ~ 80% + of the plant.

Vaporizers are designed to suppress toxic smoke emissions and deliver an effectively pure stream of inhaled cannabinoids and terpenes through much lower temperatures than combustion. This can be done in two basic ways.

Herbal vaporizers

Herbal vaporizers heat raw cannabis flowers or leaf to a temperature where the cannabinoids and terpenes evaporate, without burning or scorching the underlying leaf. This can be done at temperatures of around 180–200° C. The efficacy of herbal vaporizers was demonstrated in lab studies sponsored by Cal NORML in 1999 – 2002, which found that they effectively eliminate harmful smoke toxins and deliver clean, active cannabinoid vapors to the user.¹ Based on such evidence, herbal vaporizers have become the preferred method of administering inhaled cannabis to human subjects by medical researchers at the University of California and elsewhere. Herbal vaporizers have the disadvantage of being relatively bulky, expensive, and complicated to operate. In cheaper

¹ D. Gieringer, "Cannabis Vaporization: A Promising Strategy for Smoke Harm Reduction," *Journal of Cannabis Therapeutics*, Vol. 1 #3/4: 153-70 (2001). Gieringer & St. Laurent, "Cannabis Vaporizer Combines Efficient Delivery of THC With Effective Suppression Of Pyrolytic Compounds" *Journal of Cannabis Therapeutics* Vol. 4 #1 (2004).

models, the temperature must be carefully managed to avoid scorching the leaf.

Vape pens

Cannabis vape pens are a newer, more convenient technology that utilize concentrated extracts. The process of extraction removes the bulk of the unwanted cellulose and undesired plant material, leaving a relatively pure oil of cannabinoids and terpenes. The extract is then vaporized in a cartridge by a battery-powered electronic heater in such a manner as to prevent combustion and smoke. Done properly, this produces a nearly pure stream of active cannabinoids and terpenes with at most trace amounts of noxious, inactive byproducts.

CANNABIS VAPE PENS: ADVANTAGES AND CONCERNS

Advantages of Cannabis Vape Pens

Because of federal restrictions on research of Schedule I substances, it has been impossible to study cannabis vape pens and extracts commercially sold in California. However, the safety profile of cannabis vape pens has been demonstrated in a study using government-approved extracts, which concluded that the health hazard from vaped cannabis is less than 1/1000th that of smoking.² Similar results have been found in studies of nicotine e-cigarettes, which operate on similar principles.³ Although cannabis smoking is not as hazardous as tobacco – in particular, it hasn't been linked to lung cancer – it is known to raise the risk of bronchitis and respiratory infections. Vape pens can therefore offer valuable harm reduction benefits to users wishing to avoid exposure to smoke.

Cannabis vape devices have other important advantages over smoked marijuana. They drastically reduce second-hand smoke exposure, first because they don't emit smoke toxins, but rather vapor; and secondly because they deliver vapor only to the user while inhaling, unlike cigarettes, which constantly spew out side-stream smoke while they burn. Vaporizers likewise eliminate mischievous sparks, embers, and ashes, and don't require lighters or matches.

² J. Meehan-Atrash et al., "Aerosol Gas-Phase Components from Cannabis E-Cigarettes and Dabbing: Mechanistic Insight and Quantitative Risk Analysis," *ACS Omega* Sept 16, 2019.

³ Goniewicz et al, "Level of selected carcinogens and toxicants in vapour from electronic cigarettes," *Tobacco Control* Mar 6, 2013; and I. Burstyn, "Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks," *BMC Public Health* 2014, 14:18

CONTAMINANT CONCERNS AND REMEDIES

Cannabis vape pens have been available in California since before 2013. They were widely used without any evident problems until April, 2019, when the first case of EVALI was reported. This indicates that the source of the problem is some new additive, defect, or contaminant, not the technology itself.

Although the exact cause of EVALI is uncertain, CDC investigators have found a strong linkage with Vitamin E acetate, possibly in combination with other substances. Vitamin E acetate is an additive used to dilute cannabis oil in a manner that can't be detected by visual inspection. This is profitable for illicit manufacturers, who can make more money by diluting their cannabis extracts with vitamin E acetate. State-licensed manufacturers have no similar incentive, since their products are always tested and labeled for THC or CBD content.

The California Bureau of Cannabis Control (BCC) has reported that not a single California-licensed product has been linked to EVALI so far. The problem thus appears to be a creation of the underground market, which at last report was some three times as large as the legally regulated one. **It therefore makes no sense to ban licensed cannabis vapes; to do so will only force consumers to the underground market, where the harm is being done.**

At present, the state has no legal mechanism to restrict the use of Vitamin E acetate or other harmful contaminants. Licensed manufacturers in California are required to list all ingredients on their product labels (State Regulations §40408; 40300-40306), but there is no limit on what these might be. Flavors must be listed only if they are allergens. Although all products are tested for specified pesticides, heavy metals, solvents, etc., there is no way of ruling out other, unknown contaminants. If a new toxic ingredient is discovered, there is currently no way to ban it via regulation.

This being so, it makes sense to give BCC or CDPH (California Department of Public Health) the power to regulate additives in cannabis extracts and vape products. Included should be the power to ban any additive like vitamin E acetate that has been found to be harmful when vaporized. Ideally, a list of safe vapor additives should be compiled, similar to FDA's GRAS (Generally Recognized As Safe) list for foods. At present, no such list exists for vape extracts because research has been scant to non-existent.

For lack of better information, the state should begin by compiling a list of extract ingredients that have an established record of safe use. This would presumably include additives that were already present in commercial products in the period before EVALI appeared (pre-spring 2019). Section 40255 of the state regulations require licensees to

file a written report of their manufacturing protocols to CDPH. Cal NORML urges the state to review these protocols and compile a list of known additives and processes to help evaluate their relative risk to consumers. The FDA will soon be evaluating the safety of nicotine e-cigs; to the extent their ingredients are similar to cannabis extracts, the FDA's findings may be useful for cannabis too. However, given that FDA is currently forbidden to do cannabis testing, it would behoove California to sponsor research of our own.

While there isn't enough evidence yet to define a GRAS list for vape ingredients, it's possible to identify ingredients that are known to be unsafe and which should be prohibited. A good starting point is the U.K's list of substances not permitted in tobacco e-liquids,⁴ which includes known carcinogens, mutagens, respiratory toxins, diacetyl, and other toxins. The U.K's system of e-cig regulation has successfully avoided EVALI casualties to date. The state should consider adopting a similar list, with the obvious addition of Vitamin E acetate.

Safety of Current Vape Products

Certain types of vape products can be presumed to be safe:

- Herbal vaporizers that don't use extracts or additives but vaporize natural flowers and leaves are inherently safe and have no link to EVALI.
- Vape oils extracted from pure cannabis without any additives can likewise be presumed to be safe, insofar as they contain nothing not found in smoked marijuana. The principal constituents of cannabis oil are cannabinoids (THC, CBD et al.) and terpenes, which impart odor and flavor and have medicinal properties of their own. The remaining fraction (<5 - 20%) consists of natural waxes and residual plant matter. Because cannabis extracts eliminate most combustible material from the raw plant, and are heated to lower temperatures than in smoking, they emit substantially fewer toxins than smoked marijuana. Thus they present clear harm reduction benefits over smoked marijuana.
- Some processes, such as CO₂ extraction, remove the terpenes from the oil. Because terpenes are valued for their medicinal effects and flavor, they must be added back to the oil in order to make an effective vape product. In some cases, the same terpenes that were removed in processing are re-injected at the end. In others,

⁴ UK Discussion Paper on Submission of Notifications Under Article 20 of Directive 2014/40EU, Chapter 6 – “Advice on Ingredients in Nicotine-Containing Liquids in Electronic Cigarettes and Refill Containers,” https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/682739/ingredient_guidance_final_draft_011116.pdf Accessed 1/26/2020.

manufacturers add terpenes obtained from chemical supply houses. This is presumably safe so long as they are identical to the natural terpenes found in the plant. Problems might conceivably arise if manufacturers use other, non-standard terpenes, or add them in unusual quantities, or if the terpenes are contaminated by chemical manufacturers. So far, there is no evidence of such problems.

- Other artificial flavorings have occasionally been added to THC vape extracts, like those used in flavored nicotine e-cigs: peach, mint, strawberry, etc. To the extent they have been used in nicotine vapes without evident harm, they are presumably safe as well. At least one flavoring agent that is safe in edible use (diacetyl) is known to be dangerous when vaped, producing a disease known as “popcorn lung.” Unlike terpenes, these flavorings don’t contribute to the medical or psychoactive effects of cannabis.

- A few manufacturers add chemical excipients or diluents to their extracts in order to help them vaporize better. Popular examples are propylene glycol (PG), polyethylene glycol (PEG) and MCT oil. While some concerns have been raised about their safety profile, they have been widely used in nicotine and cannabis e-cigs for many years without any evident problems. In response to popular concern, the use of excipients and diluents in cannabis e-cigs has declined in recent years; the best manufacturers now mostly use pure cannabis oil and terpenes. Some diluent use may be useful for standardizing concentrations for consistent medical use.

- It has been suggested that defective e-cigarette hardware might in some cases emit heavy metal contaminants. Many e-cig cartridges have metal components that could conceivably leak contaminants into the vapor. The extent of such leakage, if any, is apt to be small,⁵ and there is no good evidence so far linking bad hardware to EVALI disease. E-cigarettes are imported from scores of different manufacturers, mostly in China. The best of them now use ceramic heating elements that contain no metals at all.

⁵ Farsalinos and Rodu, “Metal emissions from e-cigarettes: a risk assessment”, *Inhal Toxicol* 2018 Jun-Jul: 321-6

SUMMARY AND RECOMMENDATIONS

- 1) Cannabis vaporizers and vape pens offer important smoke harm reduction benefits to both users and second-hand bystanders, so long as they are properly manufactured.
- 2) No case of EVALI disease has been traced to a California-licensed product; rather, the epidemic is linked to products from the illicit market. **It is therefore essential that licensed cannabis vapes not be banned, since this will drive consumers to more dangerous, illicit products**
- 3) State law should be amended to give the BCC (or DPH) authority to regulate additives to cannabis extracts, including the power to ban ingredients found to be harmful on an emergency basis.
- 4) Further research is needed to determine the safety of various additives and flavorings used in vape extracts. Since the FDA lacks authority over cannabis, California should consider sponsoring research in this area.
- 5) The BCC (or DPH) should compile a list of flavorings and additives known to have been used by licensed vape manufacturers. Products in wide use before the EVALI crisis can tentatively be presumed to be safe.
- 6) Herbal vaporizers and vape pens using extracts based on pure cannabis oil may be presumed to be safe.
- 7) Lacking further evidence, cannabinoids, terpenes, flavorings and other additives that were on the market before the outbreak of EVALI may tentatively be presumed to be safe.
- 8) In the meantime, the state should consider adopting a list of prohibited additives and flavorings that are known to be toxic, like that adopted by the U.K. in their regulations of nicotine e-cigarettes.
- 9) Cal NORML strongly advocates the repeal of federal laws and DEA regulations that currently prohibit research with cannabis vapes.