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Introduction

Chairman Alexander, Ranking Member Murray, members of the Committee, I am Aaron Smith, Executive Director and Co-Founder of the National Cannabis Industry Association (NCIA), the largest national trade association dedicated to protecting state-regulated cannabis businesses, and advancing policy reforms needed to harmonize federal marijuana law with the successful medical and adult-use state cannabis programs that exist throughout the country. On behalf of our nearly 2,000 members, we thank you for the opportunity to discuss our concern over the recent illnesses and deaths associated with some THC and nicotine vape products, and support for legislation that aims to effectively legalize and regulate cannabis, eradicate the illicit market, and ultimately bring an end to vaping-related illnesses and deaths that largely result from products purchased from the illicit market.

Medical cannabis patients and adult consumers in 33 states depend upon safe, state-regulated cannabis products. As the largest national trade association representing the state-legal cannabis industry, our members' businesses depend upon delivering reliable and safe products. The recent reports of vaping-related illnesses and deaths are alarming and demand the robust investigation being undertaken by the Center for Disease Control (CDC). We would, however, urge the CDC to act with more deliberate speed to communicate their findings, even if piecemeal, to the public. There is serious concern in the marketplace and people's lives and livelihoods are at stake. Make no mistake, the legal state-regulated cannabis industry knows that any death is one death too many. Fortunately, NCIA has developed policy proposals that can be employed to help limit the illicit market, implement uniform and safe manufacturing practices, and prevent future vaping related harms.

In order to be effective, public policy aimed at reducing vaping related illnesses and deaths demands a fact-based strategy that relies on verifiable scientific evidence. As the CDC confirmed last week, many key facts surrounding recent vaping-related illnesses and deaths remain unknown. However, even as unknowns remain, CDC also confirmed that preliminary

results have found a causal link between products sold on the illicit market containing vitamin E acetate, and many of the recent illnesses and deaths.

Indeed, on November 8, 2019, the CDC released an updated statement confirming the presence of vitamin E acetate (Tocopheryl acetate) in lung fluid samples taken from multiple patients diagnosed with e-cigarette or vaping product use associated lung injury (EVALI). Vitamin E acetate is one of several unregulated additives used primarily in illicit market vaping products that CDC is investigating as a potential cause of the recent epidemic of illnesses and deaths. Laboratory testing of fluid collected from the lungs from 29 patients with EVALI submitted to CDC from 10 states found vitamin E acetate in all of the fluid samples. CDC reports that "this is the first time that we have detected a potential chemical of concern in biologic samples from patients with these lung injuries."

The affected patients used both THC and nicotine vape products. THC was identified in 82% of the samples and nicotine was identified in 62% of the samples. Suspect chemicals other than vitamin E acetate were not identified in the samples tested. CDC reports that it could not detect a range of other chemicals that might be found in vaping products, including plant oils, petroleum distillates like mineral oil, MCT oil and terpenes.

According to CDC, "these findings provide direct evidence of vitamin E acetate at the primary site of injury within the lungs." CDC cautions, however, that although it appears vitamin E acetate is associated with EVALI, there may be multiple causes of the outbreak and "many different substances and product sources are still under investigation."

In addition to a general recommendation by CDC that no nicotine or THC based vaping product be used, CDC specifically recommends that people should not buy any type of vape product off the street or modify or add any substance that is not intended by the manufacturer.

As of November 5, 2019, 2051 cases of EVALI have been reported to CDC from every state except Alaska. 39 deaths have been confirmed in 24 states and the District of Columbia.

Prior to this pronouncement, a great deal of media coverage was based on speculation. Many reports have conflated a wide variety of products with little in common except the use of a vaporizer. It is clear from this media coverage and some responsive actions at the state level that the media and government officials are not effectively educated on the varying types of vaping products. Ultimately, in order to effectively address the vaping issue, it is imperative that the media and those responsible for the public health understand the vaping market and effectively distinguish between different vaping technology. It is just as critical that they understand the dangers of an unchecked illicit market and the need to supplant that market with tightly-regulated and legal cannabis businesses.

Vaping Devices and State Regulations

In assessing how to combat vaping related illnesses, it is first necessary to understand that there are two main types vaping systems: (i) "closed system" where a cartridge is delivered to the consumer pre-filled with a nicotine or cannabis liquid, and (ii) "open system" where the consumer personally loads the material to be vaporized, which can take many forms. While CDC's investigation has not reached a final conclusion, it appears that a significant majority of vaping illnesses are tied to closed system cartridges that are filled by bad actors in the illicit market with untested adulterants, contaminants, and other unknown substances.

On the other hand, when a closed system cartridge or material placed in an open system vaporizer is purchased from a regulated, state-legal retailer, the consumer has knowledge of the ingredients and the origin of the product. Products purchased in state-legal markets are also subjected to laboratory testing for safety.

In addition to closed vs. open systems, some public figures seem unaware that many commonly used vaping systems are designed for cannabis flower and not cannabis oil. As of today, none of the recent vaping related illnesses or deaths have been tied to flower-based vaping. Nonetheless, this fact has been ignored in an adult-use state like Massachusetts that had banned all types of vaping devices and cartridges. Thus far, some state action has been to reflexively ban products instead of identifying the actual root cause of the problem. Indiscriminate bans and other clumsy policy responses will do nothing to eradicate the illicit market or improve effective regulation of the legal market.

Real solutions require that we focus on facts. Despite a great deal of speculation, preliminary reports have made clear that a high percentage of the illnesses are causally linked to cannabis or nicotine products purchased from the illicit market that contain potential adulterants and contaminants. On the other hand, products purchased from licensed operators within the growing number of state cannabis programs require testing for product safety, including screening for adulterants and contaminants.

If this trend continues, it is essential that regulators and the media accurately warn the public about the specific dangers with illicit and unregulated products and avoid making broad declarations that wrongfully implicate safe, legal, and highly regulated vaping products. The public needs accurate and actionable information from the government, particularly with regard to illegal, untested, and dangerous consumer products.

Governors in states like Massachusetts, Michigan, New York, Oregon, and Rhode Island, and local governments throughout California, have conflated two separate consumer vaping issues: (i) the rise of youth nicotine vaping and (ii) vaping related illnesses largely tied to illicit market products. Instead of differentiating between two separate issues and crafting public policy to address each issue, states have lumped the two together, thereby ineffectively addressing the main cause of these illnesses and deaths; illicit market products.

The ongoing illnesses and deaths are an unmistakable reminder of the importance of effective regulation. Americans must not continue to be seriously injured or killed by unregulated, illicit market cannabis vaping products. This may be the most urgent reason yet to strongly push for comprehensive cannabis reform at the federal level. Reform will allow the legal, highly regulated, and thoroughly tested cannabis industry to once and for all displace the illicit market actors.

Deschedule, Test, Regulate, and Displace the Illicit Market to Ensure Public Safety

On October 1, 2019, NCIA released substantive recommendations for how cannabis can be regulated at the federal level. Currently, because of marijuana's status as a Schedule I drug under the Controlled Substances Act (CSA), the Drug Enforcement Administration (DEA) is the primary federal regulator of cannabis. As a result, criminal enforcement serves as the sole

regulatory tool of the federal government over cannabis. The DEA's enforcement of cannabis regulations has solely revolved around prohibition policies that have aggressively failed to either stamp out the illicit market or allow the legal market to effectively supplant it at the national level. As of today, despite the varying health issues associated with the illicit cannabis market, there is no cohesive federal public health policy for cannabis. Federal public health policies are needed now more than ever as national support for cannabis legalization has reached 66% in favor, legal markets continue to grow and consumers face safety issues from illicit, unregulated products. In light of the climate surrounding cannabis, NCIA hopes that lawmakers will pay close attention to our recommendations, as our industry deeply believes that responsible federal regulation is what Americans deserve and expect in order to safely consume cannabis. Lawmakers and the public can find our report, Adapting A Regulatory Framework For The Emerging Cannabis Industry at www.thecannabisindustry.org. Our plan was developed by NCIA's Policy Council, a group of dedicated lawyers, entrepreneurs, doctors, scientists and other cannabis professionals dedicated to developing common sense public policies for the state-legal cannabis industry.

The first and most important step towards a comprehensive regulatory system for cannabis is for Congress to remove marijuana and its derivatives, including delta-9 tetrahydrocannabinol (THC), from the CSA, otherwise known as "de-scheduling." De-scheduling is the only way to truly reform federal cannabis policy in a sensible manner so that state regulatory programs can most successfully ensure consumer safety and pave the way for appropriate federal regulations. NCIA's proposal calls for cannabis products to be descheduled and properly regulated like other consumables (e.g. food, beverages, medications). Our plan specifically calls for regulation by the government agencies that oversee most food and drug products; primarily, the Food and Drug Administration (FDA) and the Alcohol and Tobacco Tax and Trade Bureau (TTB). If enacted, and vaping products were to fall under the FDA's purview, for example, the FDA could develop guidelines for testing cannabis vapor products for toxicants, similar to how the FDA proposes to review e-cigarette products. De-scheduling cannabis will also put an end to many of the federal policies that make it difficult for legal cannabis businesses to effectively compete with illicit operators. Eliminating the undue burdens caused by outdated laws will help ensure that unethical actors are increasingly disrupted by tightly-regulated, responsible businesses, and this in turn will decrease the number of illicit vaping products that enter the market.

NCIA's member businesses strive to improve the lives of patients and countless other Americans. In order to achieve this objective, it is imperative that we provide safe and regulated products. Voters and legislators have approved medical programs in thirty-three states and these programs have proven effective for patients. Patients and recreational cannabis consumers deserve a fact-driven regulatory response from Congress to prevent further harm. The public should have confidence in the products that legal cannabis businesses market and sell. No one is more eager than members of the cannabis industry to implement reasonable regulations.

NCIA Policy Council's Recommendations

In light of the suspected cause(s) of these illnesses and deaths, and the variance in state regulations regarding vaping products, NCIA is making the following recommendations:

- Congress is urged to immediately (i) remove cannabis from the CSA and begin to sensibly regulate cannabis in a manner similar to alcohol and other consumables and (ii) allocate funding to state medical authorities to investigate and identify the root cause of these illnesses and deaths.

- Licensed vape cartridge producers are encouraged to halt the use of any additive thickening or thinning agents without an established history of safe use in vapor products until more data is available or a rigorous safety analysis is done. In particular, given the preliminary reported association of some illness cases with vitamin E acetate, any licensed producer that has included this additive in recent vaping product batches is strongly encouraged to issue a voluntary recall of those products.

- Licensed cannabis retailers are encouraged to take steps to ensure that none of their available vape cartridge inventories have been sourced from a producer that uses vitamin E acetate.

- Cannabis vape cartridge consumers are urged to immediately cease the use of any product obtained from the illicit market and to limit future purchases of vape cartridges and other cannabis products from only state-licensed, regulated businesses.

Conclusion

The legal cannabis industry is extremely concerned about these reported illnesses and deaths. It is clear that the American public wants quality-controlled cannabis products made available for adults and patients. The recent news is, unfortunately, yet another reminder that there is no time to waste. The cannabis industry wants to provide the products voters demand with a tireless focus on improving consumer safety. We are at the ready to work collaboratively with federal lawmakers with the same commitment that we have made at the state level for over a decade. Now is the time to regulate, not ban. Please let us know how we can help to constructively move forward with much-needed legislation addressing these issues and the unintended consequences of prohibition. Lives are literally at stake.

I want to thank the Chair, Ranking Member, and the Committee for your time to discuss the prevention of vaping related illnesses and deaths through proper cannabis regulation. This topic is important to members of NCIA and to the entire legal cannabis industry. I again thank the committee for the opportunity to submit testimony today.

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