



Assembly Committees on Governmental Organization, Business & Professions, and Health Joint Informational Hearing:

**Vaping Tobacco and Cannabis Products: Health Effects
and Deficiencies in Regulation and Current Law
Wednesday, October 16, 2019
1:00 p.m., Room 4202**

INTRODUCTION

This will be the first of two hearings. This hearing will provide an overview of the issues related to vaping, including the health effects and regulatory landscape, with testimony provided by medical professionals, tobacco and vaping experts, and state government regulators. The hearing will also look into the growing popularity of e-cigarettes and vaping, and examine the overall impact on youth and general consumers.

BACKGROUND

On September 10, 2019, President Trump, Health and Human Services Secretary Alex Azar, and Dr. Ned Sharpless, the acting Commissioner of the Food and Drug Administration (FDA) announced they would issue a draft ban on most flavored e-cigarettes within several weeks. The agencies stated that the announcement was prompted by recent findings from the National Youth Tobacco Survey that indicate a rise in youth vaping, with over 25% of high school students stating they have used e-cigarettes in the past 30 days. Pursuant to a final rule from August 8, 2016, all electronic smoking devices (ESD) or electronic nicotine delivery system (ENDS) products would be required to file premarket tobacco product applications within two years; however, the FDA had delayed the requirements until August 2021. In July 2019, a federal judge overseeing a lawsuit brought against the FDA by the American Academy of Pediatrics over the delay of the rule, ruled that e-cigarette companies must submit their products for FDA review within 10 months, or by May 2020. However, the judge held that these products would be allowed to remain on the market in the interim and for up to one year while the FDA reviews the applications.

The September 10 announcement is an indication that the FDA intends to finalize enforcement guidance to require any non-tobacco flavored product (i.e. kid-appealing flavors) to be removed from the market until an application for premarket approval has been obtained under the Tobacco Control

Act. To provide a non-combustible nicotine option for adults, tobacco-flavored products will be exempt from the enforcement order. However, Acting Commissioner Sharpless stated action would be taken against tobacco-flavored products if children start to migrate to those products as well.

Prior to this announcement, in September 2018, Dr. Scott Gottlieb, the FDA Commissioner at the time, declared that youth vaping is now an epidemic, and the FDA initiated the Youth Tobacco Prevention Plan, which focuses on preventing youth access to tobacco products, curbing the marketing of tobacco products aimed at youth, and educating teens about the dangers of using any tobacco products. The FDA then issued 12 warning letters to companies that continued to advertise and sell products to youth. The FDA also sent letters to five ESD manufacturers whose products were sold to kids during the FDA's ramped up enforcement period: JUUL, Vuse, MarkTen, blu e-cigs, and Logic, which comprise 97% of the e-cigarette market. The FDA requested that these companies provide robust plans on how they will address the widespread use of their products by minors or face increased enforcement.

These federal initiatives are a result of a multistate outbreak of lung injuries related to vaping. According to the Centers for Disease Control and Prevention (CDC), as of October 8, 2019, 1,299 lung injury cases associated with using e-cigarette, or vaping, products have been reported to CDC from 49 states and one U.S. territory. Twenty-six deaths have been confirmed in 21 states, including three in California. All patients have reported a history of using e-cigarette, or vaping, products. Most patients report a history of using products containing Tetrahydrocannabinol (THC) [the psychotropic ingredient in marijuana]. The latest national and regional findings suggest products containing THC play a role in the outbreak. Health officials are advising that people avoid using vaping devices of all kinds, whether loaded with nicotine or THC from cannabis. According to the CDC, the demographics of the lung injury cases are as follows: approximately 70% of patients are male; approximately 80% of patients are under 35 years old; sixteen percent of patients are under 18 years old; and 21% of patients are 18 to 20 years old.

It should be noted that e-cigarettes are not currently approved by the FDA as an aid to quit smoking. The U.S. Preventive Services Task Force, a group of health experts that makes recommendations about preventive health care, has concluded that evidence is insufficient to recommend e-cigarettes for smoking cessation in adults, including pregnant women. However, e-cigarettes may help non-pregnant adult smokers if used as a complete substitute for all cigarettes and other smoked tobacco products. To date, the few studies on the issue are mixed. A Cochrane Review found evidence from two randomized controlled trials that e-cigarettes with nicotine can help smokers stop smoking in the long term compared with placebo (non-nicotine) e-cigarettes. However, there are some limitations to the existing research, including the small number of trials, small sample sizes, and wide margins of error around the estimates. A recent CDC study found that many adults are using e-cigarettes in an attempt to quit smoking. However, most adult e-cigarette users do not stop smoking cigarettes and are instead continuing to use both products (known as "dual use").

According to Jeff Chen, Director of the UCLA Cannabis Research Initiative, to date there has never been a study on vaping cannabis. The current vaping crisis has focused attention on the substances used to dilute cannabis oil for vaping and little is known about what happens when those products are heated. There are also concerns about the devices used to vape nicotine and cannabis, which almost exclusively come from China. The federal government has left it to the states to create testing standards, while companies in the industry have sought to reassure consumers that their cannabis oil does not contain harmful chemicals. California tests cannabis and vaping products for pesticides and other contaminants from licensed entities. The lack of research stems from a longstanding federal prohibition on cannabis that has further impacted health studies on overall vaping products, which happens to be the fastest-growing market.

Within the last month, Massachusetts announced a four-month ban on the sale of all vaping products. New York and Michigan imposed bans on sales of flavored products, and the retailers Walmart and Kroger announced they would stop selling e-cigarettes. On September 27, 2019, Washington Governor Jay Inslee, through an executive order, called for the state to impose an emergency ban on all flavored vaping products, including those that contain nicotine and THC. On October 2, 2019, Utah health officials announced emergency rules requiring all tobacco retailers that sell e-cigarettes to post notices regarding the dangers of vaping unregulated THC products, and on October 7, 2019, Hawaii state officials issued an advisory to vaping.

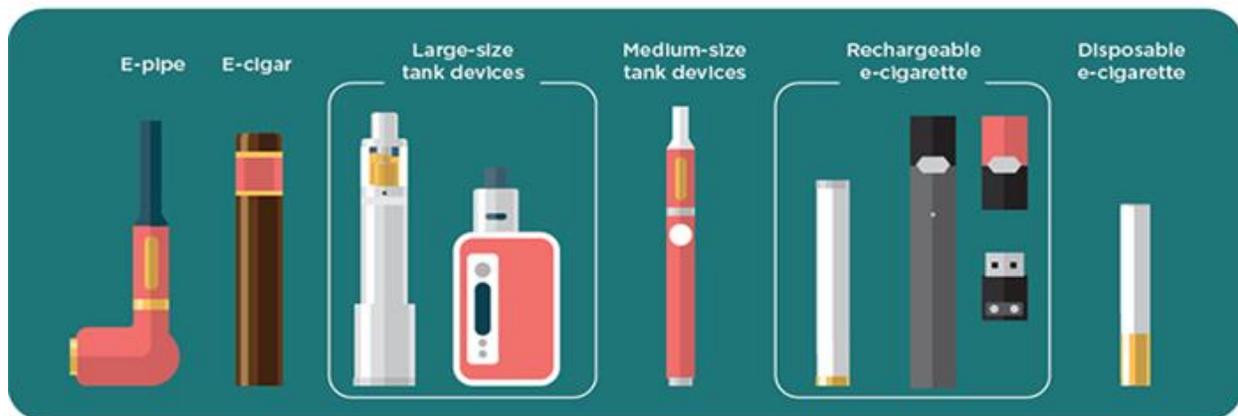
CALIFORNIA INITIATIVES

On September 16, 2019, Governor Gavin Newsom issued an executive order directing the California Department of Public Health (DPH) to launch a \$20 million statewide digital and social media public awareness campaign to educate youth, young adults, and parents about the health risks associated with vaping nicotine and cannabis products. DPH was also tasked with developing recommendations to reduce smoking among young adults and teens by establishing warning signs with health risks where vaping product are sold, and on product advertisements. The Governors' executive order also directs the California Department of Tax and Fee Administration (CDTFA) to develop recommendations to remove illegal and counterfeit vaping products from stores and include nicotine content in the calculation of the existing tax on electronic cigarettes. On September 24, 2019, DPH issued a health advisory urging everyone to refrain from vaping, no matter the substance or source.

DPH, other states, the CDC, the FDA, local health departments, and health care providers are investigating what is in the vape materials that is making people sick. In the health advisory DPH notes that, "All individuals put themselves at risk any time they inhale a foreign substance into their lungs. The risk of vaping for any individual may include serious illness and death. Vaping is not just a concern for youth; the vaping cases under investigation affect youth and adults alike."

VAPORIZERS, E-CIGARETTES, AND ENDS

According to the FDA, vapes, vaporizers, vape pens, hookah pens, electronic cigarettes (e-cigarettes or e-cigs), and e-pipes are some of the many terms used to describe ENDS. ENDS are noncombustible tobacco products. These products, or devices, use an “e-liquid” that may contain nicotine, as well as varying compositions of flavorings, propylene glycol, vegetable glycerin, and other ingredients. The liquid is heated to create an aerosol that the user inhales. ENDS may be manufactured to look like conventional cigarettes, cigars, or pipes. Some resemble pens or USB flash drives. Larger devices, such as tank systems or “mods,” bear little or no resemblance to cigarettes. These devices are also used to vaporize cannabis.



Use of e-cigarettes, now the most popular tobacco product among teens, has jumped 78% among high school students compared with 2017, with 20.8% (more than 3 million) of high schoolers now using e-cigarettes, according to new FDA data. The data also show that more than half of those high schoolers (51.2%) use menthol- or mint-flavored e-cigarettes. Research has demonstrated that flavored tobacco products play an important role in youth vaping. Almost a third of the middle and high school students who used e-cigarettes in 2016 said the availability of flavors is a main reason they used the products, according to a report from the CDC and the FDA. A study that included both middle and high school students found that 43% of youth who ever used e-cigarettes tried them because of appealing flavors. The majority of youth e-cigarette users think they vaped only flavoring, not nicotine, the last time they used a product, according to an annual national survey of more than 40,000 students from the University of Michigan *2016 Monitoring the Future* study, even though 99% of e-cigarettes sold in most brick-and-mortar stores contain nicotine. California monitors smoking rates among high school students using the California Student Tobacco Survey, administered by DPH on a biennial basis. One in eight California high school students currently use tobacco products, with the most used product among all student being ESDs (10.9%). In addition, 86.4% of youth tobacco users reported using flavored tobacco products

HEALTH IMPACTS OF VAPING

While there is little research on the health effects of vaping THC, in light of the recent outbreak of vaping related injuries/illnesses, the CDC recommends while the investigation is ongoing, that people consider refraining from using e-cigarette, or vaping products, particularly those containing THC. Adults who used e-cigarettes containing nicotine to quit cigarette smoking are encouraged not to return to smoking cigarettes, and anyone who recently used an e-cigarette or vaping product having symptoms like those reported in this outbreak, see a healthcare provider.

The CDC also states that anyone who uses an e-cigarette or vaping product should not buy these products (e.g., e-cigarette or vaping products with THC or Cannabidiol (CBD) oils) off the street, and should not modify or add any substances to these products that are not intended by the manufacturer. The CDC notes that youth, young adults, and pregnant women should not use e-cigarette or vaping products and adults who do not currently use tobacco products should not start using e-cigarette or vaping products.

The CDC's recommendations are bolstered by a growing body of research on the effects of e-cigarette use. A survey of recent studies, published in 2019 in the *American Journal of Respiratory and Critical Care Medicine*, *Journal of the American College of Cardiology*, and *Cardiovascular Toxicology*, found that e-cigarette aerosol with nicotine caused a significant increase in heart rate and arterial stiffness, having an acute impact on vascular and pulmonary function. A Yale study published in July of 2019 in the *American Journal of Preventative Medicine*, focused on the effects of the common flavoring vanillin, which is banned from combustible cigarettes, but allowed in e-cigarettes, and was found to irritate airways when combined with the acetals (molecules) in the aerosol, also known as vapor, produced by JUUL. A March 2018 Dartmouth study, published in the peer reviewed *Public Library of Science Journal*, concluded that, based on existing scientific evidence related to e-cigarettes and optimistic assumptions about the relative harm of e-cigarette use compared to cigarette smoking, e-cigarette use currently represents more population-level harm than benefit. The study also shows that, for every additional adult who quits smoking using e-cigarettes; there are 80 additional youth who initiate daily tobacco use through e-cigarettes.

Although there have been claims that e-cigarettes assist in quitting smoking, e-cigarettes are not currently approved by the FDA as a quit smoking aid. The U.S. Preventive Services Task Force, a group of health experts that makes recommendations about preventive health care, has concluded that evidence is insufficient to recommend e-cigarettes for smoking cessation in adults, including pregnant women.

TOBACCO LAWS AND REGULATIONS

Although there are robust combustible tobacco laws and regulations at the federal level, e-cigarettes have not yet been the subject of final federal regulations. In 1992, Congress passed

Section 1926 of Title XIX of the federal Public Health Service Act, commonly called the Synar Amendment. The Synar Amendment requires states to pass and enforce laws that prohibit the sale of tobacco to individuals under 18 years of age. It also requires federal alcohol and substance abuse block grant funding to be applied to enforce state law in a manner that can reasonably be expected to reduce the illegal sales rate of tobacco products to minors. Up to 40% of the block grant funding can be withheld from states for not complying with the Synar Amendment. In response to the Synar Amendment, in September 1994, the Stop Tobacco Access to Kids Enforcement Act (STAKE Act) was signed into law in California to address the increase in tobacco sales to minors and fulfill the federal mandate. The STAKE Act created a new statewide enforcement program authorizing regulatory actions against businesses that illegally sell tobacco to minors.

Federal law banning cigarette advertisements on television and radio went into effect in 1971; however, smokeless tobacco products were not banned until 1986. The Master Settlement Agreement (MSA) is an accord reached in November 1998 between the state Attorneys General of 46 states (including California), five U.S. territories, the District of Columbia, and the five largest tobacco companies in the U.S. concerning the advertising, marketing, and promotion of tobacco products. In addition to requiring the tobacco industry to pay the settling states approximately \$10 billion annually for the indefinite future, the MSA set standards for, and imposed restrictions on, the sale and marketing of cigarettes by participating cigarette manufacturers including targeting youth, using cartoons to advertise tobacco products, using brand-name merchandise, and sponsoring youth-oriented events. E-cigarettes are not part of this agreement. Under the MSA, states must pass laws requiring non-participating manufacturers to make payments to the state based on their cigarette sales, and, to diligently enforce the payments requirements by tracking all cigarettes sold in the state.

In California, e-cigarettes are included in the definition of tobacco products and the same limits apply to e-cigarettes as to combustible cigarettes, including limits on where they may be used. Existing California law prohibits the sale of tobacco products, including electronic cigarettes to individuals under age 21, but does not limit or restrict the types of flavors of electronic cigarettes. Recent efforts at the state and local level have focused on restricting the sale of tobacco products instead of advertising practices to avoid First Amendment challenges. Over 30 cities in California have passed local ordinances that ban the sale of flavored tobacco products. For example, the City of San Francisco recently banned the sale of all flavored tobacco products and e-cigarettes, including mint and menthol. The Los Angeles County Board of Supervisors voted unanimously on October 1, 2019, to ban flavored tobacco products, including menthol, taking effect in 30 days from the vote.

Approved by voters in 2016, Proposition 56 increased taxes on cigarettes and other tobacco products, including e-cigarettes, by \$2.00 starting in April 2017. It should be noted that that the

current vapor product tax is collected based on a percentage of the wholesale price of the end product sold to the consumer. The Proposition specifically allocates \$30 million of annual revenue to the California Department of Justice (DOJ). These funds support local agencies to enforce tobacco-related statutes and ordinances, including reducing the illegal sale of tobacco products to minors. Grantees may use grant funds to enforce state and local laws related to the illegal sale and marketing of tobacco products to minors and youth including: retailer compliance checks, retailer training programs, installation of signage, youth outreach, tobacco retail license inspections, and/or preventing and deterring use of tobacco products on school premises. On October 2, 2019, the Attorney General announced that 76 local agencies would receive a total of \$30.5 million in Proposition 56-authorized funds for 2019-20 through the DOJ's Tobacco Grant Program. The local entities, which include school districts, police departments and sheriff's offices, can use the money to hire additional officers and roll out enforcement programs and educational outreach initiatives.

In addition to being required to verify the purchasers' age for tobacco sales, retailers of cigarettes and tobacco products in California must have a Cigarette and Tobacco Products Retailer's License. As of June 9, 2016, state law expanded the definition of a tobacco product for cigarette and tobacco products retail licensing purposes to include nicotine products, electronic nicotine or other vaporized liquid delivery devices, and any component, part, or accessory of a tobacco product. Effective January 1, 2017, any retailer that sells any product included in the expanded definition of tobacco products is required to obtain and maintain a Cigarette and Tobacco Products Retailer's License from the CDTFA in order to engage in the retail sale of these products. A retailer's license is valid for a 12-month period, is not assignable or transferable, and must be renewed annually. A license fee payment is required for each retail location at initial registration, every year at the time of renewal. Many cities also have local licensing requirements, which may be more restrictive than state licensing requirements.

DPH also enforces the STAKE Act and its enforcement authority includes conducting unannounced inspections of retailers selling tobacco products to ensure retailers are not selling to youth. According to DPH, it conducted 4,675 compliance inspections and collected \$265,100 in civil penalties in fiscal year (FY) 2018-19. Currently, DPH is required to notify the CDTFA within 60 days of the final adjudication of a retailer's third, fourth, or fifth violation within a five-year time frame, however, DPH did not have any retailers that fit these criteria in FY 2018-19. DPH received an additional \$1.9 million in local assistance funding in FY 2019-20 to allocate grants to local entities for enforcement activities. According to CDTFA as of August 1, 2019, there are 30,685 registered cigarette and tobacco retail locations in California.

CANNABIS LAWS AND REGULATIONS

The regulation and study of the cannabis industry is particularly complex. Although the federal government considers cannabis a controlled substance, 33 states now allow its use for

either recreational or medicinal purposes, or both. Hundreds of cannabis products are sold, legally and illegally, such as THC oil, or cannabis oil with THC. The FDA has warned some sellers of cannabis product supplement not to make health claims, but so many are doing so that the agency cannot monitor them all. Liquid nicotine and THC, sometimes sold in cartridges for use in vaping devices can each contain oils that may be safe to swallow but can damage the lung when vaporized into a mix of unknown chemicals. The CDC has noted that many vaping injuries have been linked to unregulated THC products.

California first legalized cannabis for medical consumption through Proposition 215, also known as the Compassionate Use Act, in 1996. Proposition 215 protected qualified patients and primary caregivers from prosecution related to the possession and cultivation of cannabis for medicinal purposes. The Legislature passed the Medical Cannabis Regulation and Safety Act (MCRSA) in 2015. MCRSA established for the first time, a comprehensive statewide licensing and regulatory framework for the cultivation, manufacture, transportation, testing, distribution, and sale of medicinal cannabis to be administered by the Bureau of Cannabis Control within the Department of Consumer Affairs, DPH, and the California Department of Food and Agriculture.

Shortly following the passage of MCRSA in November 2016, California voters passed Proposition 64, the "Control, Regulate and Tax Adult Use of Marijuana Act" (AUMA), which legalized adult-use cannabis. In California, licensed cannabis retailers are required to sell products obtained from a licensed cannabis manufacturer that have been tested by a licensed laboratory. Cannabis products sold by licensed sources are tested for a variety of chemicals, pesticides, microbial impurities, and heavy metals. Under MCRSA, DPH was given the duty of promulgating regulations governing the labeling of all manufactured cannabis products, including determining a universal symbol to be used to mark all edible cannabis products.

DPH's Manufactured Cannabis Safety Branch (MCSB) released its final regulations in January of 2019. Under these regulations, a universal symbol must be placed on an inhaled product container, like a vape cartridge, if that container is separable from the outer-most packaging, like a vape pen. Existing emergency regulations required the universal symbol to be at least one-half inch by one-half inch and to be black in color.



CONCLUSION

Vaping has reached epidemic proportions across the nation and in California. The detrimental impact of smoking on health has been documented for many years and much like tobacco-use, vaping can be considered a risk factor for vascular and pulmonary diseases, as discussed above. Exposure to tobacco smoke is a risk factor for chronic diseases and is considered a human carcinogen. Acute effects of secondhand smoke are serious and include increased frequency and severity of asthma attacks, respiratory symptoms such as coughing and shortness of breath, and respiratory infections such as bronchitis and pneumonia. In addition, using tobacco or being exposed to tobacco smoke during pregnancy is detrimental in fetal development and increases the risk of sudden infant death syndrome.

The safety and long-term health effects of using e-cigarettes or other vaping products are not well known. Relating to the current crisis, federal and state officials have reported hundreds of total possible cases of pulmonary disease and several deaths related to vaping. State and federal health authorities state that the latest finding from their investigation into lung injuries suggest products containing THC play a role in the outbreak, however no single product or substance has been linked to all lung injury cases. According to the CDC, “THC use has been associated with a wide range of health effects, particularly with prolonged heavy use. The best way to avoid potentially harmful effects is to not use THC, including through e-cigarette, or vaping products.

Although the economic costs of vaping to society is not well established, the economic costs of smoking nationwide is more than \$300 billion a year, including nearly \$170 billion in direct medical care for adults and more than \$156 billion in lost productivity due to premature death and exposure to secondhand smoke. The 2012 California DPH State Health Officer's Report on Tobacco Use and Promotion in California estimated that adult tobacco related health care expenditures cost California \$6.5 billion that year, or about \$400 per taxpayer. Those figures did not include other health care costs for children, costs resulting from secondhand smoke exposure, the value of lost time/productivity, or lives lost.

The Governor’s initiatives are prudent first steps to addressing the growing vaping epidemic but more needs to be done to address the long-term health and economic cost of vaping, especially curbing its use among the youth. A second joint hearing, yet to be scheduled, will focus on how best to solve the problem, and how to identify and address obstacles to reducing the incidence of vaping, and the associated health risks.