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Danger, Danger Anticipating New Kratom and Vaping Claims and Litigation

Originally, both Kratom and electronic cigarettes (e-cigs, vaping devices, etc.) were marketed as potentially healthy alternatives to tobacco smoking and other controlled substances. As the use of both these and similar products increase, the dangers associated with their use are becoming more and more apparent. Moving forward, the insurance industry and defense counsel face a growing area of potential new claims and litigation over the next few years.

I. History of Kratom and Vaping

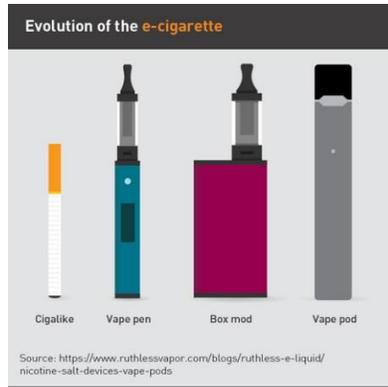
For thousands of years, people have been enjoyed smoking tobacco leaves, and the effects that ingesting nicotine can provide. Over the past several decades, as research has evolved, the public has been made aware of the dangers of smoking cigarettes, which are now known to cause cancer and heart disease. As such, people have sought alternatives to satisfy the high that nicotine provides without the dangers associated with smoking. The “e-cigarette”, as we know it today, was created by a Chinese smoker and pharmacist, Hon Lik, in 2003. Lik, who at one point was smoking up to three packs of cigarettes a day, was inspired to invent a new device after his own father, also a smoker, died of lung cancer. These electronic cigarettes, also known as “vape pens” or “vaping devices”, vaporize a flavored liquid rather than burning tobacco like more traditional cigarettes. E-cigarettes feature a replaceable inhaler cartridge containing vegetable glycerin and/or polyethylene glycol, flavoring, and nicotine. With every inhalation, a sensor triggers a vaporizer to heat a small amount of liquid flavoring. The liquid turns to vapor and is drawn into the user’s mouth. In theory, since vaping does not burn tobacco, it should be safer than conventional cigarette smoking. A main ingredient in the liquid cartridges, polyethylene glycol, is FDA-approved and is used in many consumer products. However, a 2009 study by the U.S. Food and Drug Administration found that e-cigarettes which they studied “contained detectable levels of known carcinogens and toxic chemicals to which users could potentially be exposed.”

Kratom is a botanical product made from *Mitragyna speciosa*, a tropical evergreen tree found in Southeast Asia. As a large evergreen tree, Kratom can grow upwards of 80 feet tall while producing leaves and flowers. Its first documented use for medicinal purposes developed in the early 19th century. Traditionally, the chopped fresh or dried leaves of the tree were chewed, smoked, or made into tea. Historically, it was mainly used by working class people of Thailand, Malaysia, Indonesia, and many other Southeast Asian countries to treat chronic coughs, diarrhea, intestinal-based illnesses, and much more. Farmers and laborers would chew on Kratom leaves so that its effects provided long-lasting relief from pain and depression. Likewise, like coffee, Kratom has been known to produce mild stimulant-like effects, a small benefit for those taking part in tiring physical labor. Kratom has both opioid and psychostimulant-like subjective effects. The effects of Kratom in humans are dose dependent. Small doses produce stimulatory effects resembling the stimulant effect of drugs such as cocaine or amphetamines, while larger dosages tend to be associated with sedative-narcotic effects that resemble drugs such as opiates.

II. Public Availability

One need not travel very far before encountering a “vape shop” or other small store marketing Kratom, e-cigarettes, etc. Kratom is available in both brick-and-mortar stores as well as online, and at tea shops. There are hundreds of websites that can be found selling Kratom, where the quantity and prices will vary drastically based on the form and quality of product. The most common forms of Kratom available include capsules, pressed tablets, powders, teas, and extracts.

Similarly, e-cigarettes are available both online and in retail stores across the world. E-cigarettes are sold at locations that traditionally sell cigarettes and other tobacco products, such as convenience stores, gas stations, pharmacies, and tobacco shops. They are also sold at non-traditional retailers such as online retailers or vape shops. When e-cigarettes first began entering the market around 2007, some devices were designed to resemble regular cigarettes, while others looked more like cigars, pipes, pens and even USB flash drives. To account for the diversity in product design, some researchers have classified e-cigarettes as first, second or third generation devices. A first-generation e-cigarette is one that closely resembles a cigarette and is disposable. A second-generation e-cigarette is a larger, usually pen-shaped device, that can be recharged. A third-generation e-cigarette refers to devices that do not resemble a combustible cigarette and often have very large and sometimes customizable batteries. Some parts may be replaceable, which is why they are sometimes called “mods.” These devices are refillable. More recently, e-cigarettes that have a sleek, high-tech design and easily rechargeable batteries have entered the market.



III. Current Landscape

In recent years, Kratom has become popular in the European Union, United States, and other countries (e.g., Japan) as a recreational novel compound. A variety of related products are easily accessible from local shops and increasingly available for sale online, where the exact content is not always verified. Many different formulations are available, including raw leaves, capsules, tablets, powder, and concentrated extracts. Prices also vary between countries, depending on the type and amount of the purchased product. These products are currently controlled only in a small number of European Union Member States, such as Denmark, Latvia, Lithuania, Poland, Romania, and Sweden. Kratom is largely uncontrolled in the United States at the federal level. This means that all parts of the plant and its extracts are legal to cultivate, buy, possess, and distribute without a license or prescription, and, when sold as a supplement, sales must conform to U.S. supplement laws. In February 2014, the Food and Drug Administration (FDA) issued "Import Alert 54-15" that provides customs and border agents broad authority to seize Kratom products from several suppliers outside the U.S. However, some states, individual cities and counties across the U.S. have initiated efforts to regulate Kratom. Six states (Alabama, Arkansas, Indiana, Rhode Island, Vermont, and Wisconsin) currently classify Kratom as a schedule 1 controlled substance, making the substance illegal in all areas of use, possession, and purchase. Other states restrict the use to individuals over the age of 18 (Illinois and New Hampshire) or individuals over the age of 21 (Tennessee). Kratom is legal in Colorado, with an exception in Denver where it is "illegal for human consumption."

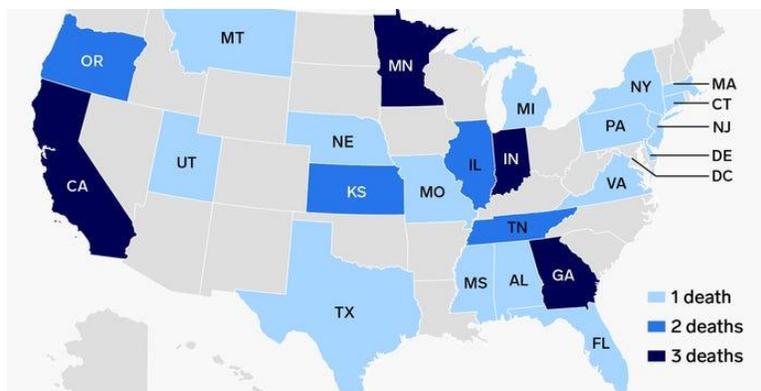
Unlike prescription drugs, dietary supplements do not need approval from the U.S. Food and Drug Administration. Although Kratom is legal in most places in the country as an herbal supplement, the FDA has warned against its use. The agency has called it "opioid-like" and cited concerns that it might pose an addiction risk. Some patients report that they have had a good experience with Kratom for treating pain, mood disorders and opioid addiction. Medical providers often caution that the positive effects are not supported by medical literature. Most pharmacologic and therapeutic evidence about

Kratom comes from anecdotal reports and patient experiences. More than half of the available scientific literature on Kratom has been published since 2012, and there are few, if any, controlled clinical trial results that have been published. Recently, a team led by Dr. Victor Navarro, head of gastroenterology at Albert Einstein Healthcare Network in Philadelphia, looked at 404 cases of liver damage from dietary supplements. Eight of the cases, which occurred between 2007 and 2017, were tied to Kratom. Five patients used Kratom to get high, and one used it for joint pain. All used the supplement for two to six weeks before signs of liver damage appeared. Five patients had jaundice (a yellowing of the skin), six had itching, five had abdominal pain, and three had fever. Six patients were hospitalized, and all improved without the need for a liver transplant.

According to the FDA, there is no scientific data to back up claims regarding any purported health benefits of Kratom. Consumers are relying on incomplete information when deciding whether to take drugs/medications that contain Kratom. The FDA believes companies selling products containing Kratom are taking advantage of opioid addicts looking for a safe way to recover from addiction. Additionally, the FDA has found that some Kratom products are contaminated with salmonella, have high levels of heavy metals, and microorganisms that have the potential to cause serious illnesses.

Both e-cigarettes and regular cigarettes contain nicotine, which research suggests may be as addictive as heroin and cocaine. Many e-cigarette users get even more nicotine than they would from a tobacco product — you can buy extra-strength cartridges, which have a higher concentration of nicotine, or you can increase the e-cigarette's voltage to get a greater hit of the substance. The Centers for Disease Control and Prevention (CDC) has linked vaping to 1,479 cases of a mysterious lung disease over the last six months. The CDC, FDA, state and local health departments, and other clinical and public health partners are calling this lung disease EVALI, short for "e-cigarette/vaping associated lung injury," and often refer to the emergence of the disease as an "outbreak." At least 33 people have died from EVALI as of December 2019. The illness is marked by chest pain, shortness of breath and vomiting, and it *has largely affected young people*. Most cases -- almost 80% -- involve e-cigarette users younger than 35, and another 15% are younger than 18. Vitamin E acetate has recently been found in the lungs of sick vapers nationwide. "When vitamin E acetate is inhaled, it may interfere with normal lung function," according to CDC Principal Deputy Director, Anne Schuchat.

Deaths in United States linked to Vaping.



Among youth, e-cigarettes are currently more popular than any traditional tobacco product. In 2015, the U.S. surgeon general reported that e-cigarette use among high school students had increased by 900 percent, and 40 percent of young e-cigarette users had never smoked regular tobacco. Because the e-cigarettes industry is largely unregulated at the federal level, it is difficult to know exactly what is in any single vape.

Although relatively new, there is preliminary research also suggesting that vaping fumes may cause risks to bystanders in the form of “secondhand fumes.” Vaping industry professionals refer to these fumes as water vapor, while opponents refer to these fumes as secondhand aerosol. Data from the U.S. National Youth Tobacco Survey found that about one-third of middle and high school students were exposed to vaping aerosols in 2018. Researchers have stated the trend is concerning because they believe several possibly hazardous chemicals are released by e-cigarette vapor, including nicotine, heavy metals, aldehydes, glycerin, and flavoring substances. Most studies have concluded that passive exposure may pose a health risk to bystanders, particularly vulnerable populations such as children and teens. The World Health Organization (WHO) recommends that electronic smoking devices (ESDs) not be used indoors, especially in smoke-free environments, to minimize the risk to bystanders of breathing in the aerosol emitted by the devices and to avoid undermining the enforcement of smoke free laws. The American Association for Cancer Research and the American Society of Clinical Oncology supports prohibiting the use of ESDs in smoke free spaces until the safety of second and third-hand aerosol exposure is established.

On a federal level, the current administration has voiced a promise to push for a ban on flavored e-cigarettes. The FDA did not gain regulatory power over e-cigarettes until 2016, so many popular brands that launched before that date, including market leader, Juul, are currently available for purchase despite lacking explicit FDA authorization. On August 8, 2016, the Deeming Rule went into effect, extending the FDA’s tobacco product authority to previously unregulated categories such as Electronic Nicotine Delivery Systems (ENDS), including e-liquids and vapor devices, cigars, hookah, and pipe tobacco. Now, these items deemed tobacco products and their components and parts are subject to the Tobacco Control Act, including the requirement that all “new”

products first marketed or modified after the February 15, 2007 grandfather date obtain FDA premarket authorization. The FDA has given manufacturers until May 2020 to retroactively apply for authorization; if at that point they cannot prove their products are “appropriate for the protection of public health,” they may be removed from the market. Those intending to manufacture, import, package, label, advertise, promote, sell, and distribute Electronic Nicotine Delivery Systems (ENDS) must adhere to the mandates. Regulations include restricting sales of e-cigarettes to customers age 18 and older, reporting detailed ingredient lists, providing tobacco health documentation, posting warning statements on packaging and advertisements that state potential risks, among other rules. The Trump Administration, in September 2019, announced a plan to pull youth-friendly flavored e-cigs from the market, at least until FDA applications are complete. President Donald Trump called vaping a “problem” and his Health and Human Services Secretary, Alex Azar, said the government would force companies to remove flavored vaping products from the market. This federal policy has not yet been finalized.

A growing number of state and local governments have taken steps to regulate the sale, marketing and use of e-cigarettes to protect the health of users, reduce youth initiation to nicotine and tobacco products, and promote enforcement of tobacco-free laws.

- Michigan - In early September, Michigan became the first state to announce its intent to limit the sale of vaping products, when Gov. Gretchen Whitmer said she would issue an emergency ban on the online and retail sale of nicotine vaping products in any flavor except tobacco. The emergency ban was made official on September 18, 2019 and was set to last 180 days. Retailers were given two weeks to comply with the policy. But on October 15, 2019, a Michigan Court of Claims judge sided with retailers who claimed in a lawsuit that Whitmer overstepped her authority by enacting the ban. The judge’s injunction, which lasts six months, means shops can once again sell flavored vaping products.
- New York - On September 17, 2019, became the first state to implement a statewide ban on most flavored nicotine vaping products, just days after Gov. Andrew Cuomo called for emergency action. Just before the ban was set to take effect October 4, 2019, the New York State Appellate Division placed a hold on the ban, allowing retailers to continue selling their products. Jurisdiction passed back to an Albany County Supreme Court judge, who will decide whether to grant the Vapor Technology Association, an industry group, a preliminary injunction on the ban. Meanwhile, the New York City Council has approved a ban on nearly all flavored e-cigarettes and e-liquids in New York City, which will take effect around July 1, 2020.

- Massachusetts - On September 24, 2019, Gov. Charlie Baker declared a public health emergency in the face of more than 500 vaping-related lung illnesses and at least seven deaths reported to the U.S. Centers for Disease Control and Prevention (CDC), including five illnesses in Massachusetts. Baker also announced the country's strictest vaping prohibition yet: a four-month, statewide ban on online and retail sales of all marijuana and tobacco vaping products, flavored or otherwise. Massachusetts' policy went into effect immediately and lasts through January 25, 2020.
- Rhode Island - The day after Massachusetts' ban was announced, Rhode Island Gov. Gina Raimondo signed an executive order directing the state's Department of Public Health to ban the sale of flavored e-cigarettes in the state. It will be in place for 120 days afterwards. The state can then extend it for another 60 days.
- Montana – On October 8, 2019, Gov. Steve Bullock directed Montana's Department of Public Health and Human Services to draft emergency administrative rules that would ban the sale of all flavored e-cigarettes, including those containing THC and CBD, for 120 days. The rules were set to take effect on October 22, 2019, but on October 19, 2019, a Montana judge signed a temporary restraining order that blocked the policy, after vape shop owners filed a lawsuit claiming the action was overly restrictive and could put stores out of business.
- Washington – On October 9, 2019, health officials passed an emergency rule banning the sale of flavored vaping products. The 120-day rule went into effect following an executive order from Gov. Jay Inslee, who called on the state's Board of Health to ban all flavored vaping products, including those containing THC.
- Oregon - On October 11, 2019, health officials filed rules that would forbid the sale of flavored nicotine and cannabis vaping products for six months, and subject repeat-offending retailers to fines of up to \$500 per violation, per day. As in other states, however, Oregon's policy was partially blocked by an appeal judge, who halted the ban on nicotine products. The ban on cannabis products was not affected.
- California - Though California has not enacted a statewide ban on vaping products, Gov. Gavin Newsom issued an executive order focused on curtailing the state's youth vaping epidemic. Among other actions, the order allocates at least \$20 million for a "vaping awareness campaign," and calls on state agencies to develop recommendations for limiting the sales of vaping products to anyone younger than 21, and the sales of illegal and counterfeit vaping products broadly. The order also requests that the California Department of Public Health develop standards requiring e-cigarette retailers to post warning signs about the health risks of

vaping. Newsom has also said he would like to ban flavored e-cigarettes outright but cannot do so through executive action alone.

IV. Potential Liability and Litigation

While relatively uncharted territory, new litigation continues to surface related to both vaping and Kratom. As noted above, some of the initial litigation has come from vape shops and manufactures or industry groups who have challenged the implementation of state laws seeking to stop or ban the use or sale of vaping devices.

Wrapped in the dispute about Kratom’s safety is the question about who may be held responsible if someone is hurt or dies after using it. Several plaintiff personal injury firms now market Kratom class action suits. A case currently pending in Pinellas County, Florida involves a mother who filed a negligence lawsuit against three local bars which all serve Kratom tea, as she alleges that her daughter suffered psychotic episodes, hallucinations, and frontal lobe damage to her brain after regularly consuming Kratom tea over a four-year period.

E-cigarette litigation is varied and still in the early stages. Plaintiffs have brought cases alleging false advertising, lack of health warnings, and personal injuries—including lung disease, nicotine poisoning, and combustion of devices and batteries that caused severe burns. Products liability actions have included claims for defective design and inadequate warnings. Several class actions also have been filed, including one in California alleging dangerous levels of diacetyl and other chemicals and lack of warning labels about the known links to popcorn lung, emphysema, and chronic obstructive pulmonary disease. Other class actions have alleged false advertising and marketing claims about e-cigarettes’ purported ability to help users quit smoking, failure to warn or inform consumers of associated health risks, and misleading consumers about e-liquid ingredients and their safety.

Recently, Siddharth Breja, a former senior vice president of global finance at Juul Labs filed suit against the e-cigarette manufacturer, claiming he was retaliated against for raising concerns about allegedly contaminated nicotine pods. Breja, who worked at the San Francisco-based company from May 2018 to March 2019, filed the lawsuit in the U.S. District Court in California alleging that Juul sent to market at least one million mint-flavored e-cigarette nicotine pods that were contaminated, and against Mr. Breja's insistence and protests, “refused to recall those contaminated pods or even issue a product health and safety warning.” There is potential for similar suits to be filed against other manufacturers as well.

Potential Liability Claims

Business Type/Entity	Possible Claims/Litigation
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Manufacturers (e-cigs)	<ul style="list-style-type: none"> • Product Liability • Failure to Warn. • False Advertising • Defective products (e-cig “explosions”) • Violation of state consumer protection statutes • “Second-hand” vapor ingestion injuries
Retail Sellers (e-cigs / Kratom)	<ul style="list-style-type: none"> • Product liability (stream of commerce) • Strict liability (sales to minors, etc.) • Failure to Warn
Bars/Restaurants/Hotels	<ul style="list-style-type: none"> • Overserving - “Dram Shop” Claims • Violations of “Smoke Free” regulations
Medical	<ul style="list-style-type: none"> • Failure to diagnose injuries caused by Kratom or e-cigs.
Drivers/Vehicle owners/businesses	<ul style="list-style-type: none"> • Personal injury claims for “under the influence” of Kratom or e-cigs • Injuries caused by distracted driving while using e-cigs, etc.
Employers	<ul style="list-style-type: none"> • Discrimination via use of products by employees • Behavioral Risk – Operation of machinery or automobiles while using products

V. Small Business Impact

It may be difficult to convince a small business to warn their patrons about potential risks associated with Kratom if they do not believe the risks exist. Many vendors became involved in the Kratom business because they believe in the product in the first place and do everything in their power to dispel any negative reactions to the substance. These retailers are often at odds with federal agencies, such as the FDA, over the marketing, use, and risks associated with Kratom use. Commonly, these companies neglect to warn customers of the potential dangers that have been linked to the popular “supplement”. These distributors, manufacturers, or those in connection with Kratom sales do not likely understand the liability they may face for failing to warn consumers of the safety, contraindications and health risks associated with their purchase of the product, which, unlike traditional cigarettes, rarely come with a conspicuous package warning label.

E-cigarette companies, such as Juul, may have their own legal counsel or research departments that can debate the efficacy of issuing product warnings, and evaluate their potential for facing legal liability or other risks in marketing their products. However, smaller retailers, such as the local brick-and-mortar vape shop, may not realize the potential risks and liability to which they expose themselves by selling these products. The FDA has warned that if you operate a vape shop that mixes or prepares liquid nicotine or nicotine-containing e-liquids or create or modify any type of electronic nicotine delivery system, you may be considered a manufacturer. As a result, some vape shops may have legal responsibilities as both manufacturers and retailers of tobacco products.