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Cannabis, CBD and Hemp Go Global – Opportunities for Insurance and Legal Professionals

I. Will Hemp-Derived CBD Be Fully Legal with Passage of the 2018 Farm Bill? Not Quite…

Public interest in the potential health benefits of CBD (cannabidiol) is responsible for a whole new market segment of health and wellness foods and supplements that features CBD as an ingredient. CBD is one of more than 100 cannabinoids in the cannabis plant, but unlike THC (tetrahydrocannabinol), CBD is not psychoactive and won't get the user "high." The CBD market is expected to top $591 million this year, and with federal protections could grow to $22 billion by 2022. Fueling this trend is scientific and anecdotal evidence of CBD's effect on anxiety, pain, inflammation, nausea and seizures, as well as its value in fighting the opioid crisis.

Given this intense interest, many ask "Is CBD legal?" Most who have sought this answer online find overly simplistic conclusions or, worse, legal advice that is dangerously wrong. When considering the legality of CBD, one must ask two equally important questions: Is CBD legal under the Controlled Substances Act (CSA)? Is CBD legal under U.S. food and drug laws? Most people tend to focus on the former due to media coverage on the evolving legal protections at the federal level, including new protections for hemp-derived CBD that are now confirmed to be included in the 2018 Farm Bill. Though not as sexy as the CSA, the Federal Food, Drug, and Cosmetic Act (FTCA) very likely presents the greater long-term problem for the CBD industry because there are few available protections to the legal risks presented by the FTCA.

To appreciate the impact of the 2018 Farm Bill on the legality of hemp-derived CBD, it is necessary first to address the current legal landscape and relevant federal agencies.

Marijuana versus Industrial Hemp

Under federal law, marijuana is a Schedule I controlled substance and illegal for any reason. The CSA defines marijuana as "all parts of the plant Cannabis sativa L − and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or resin."

Industrial hemp is a subspecies of cannabis characterized by fibrous stalks and very low levels of THC. It is an agricultural commodity with many uses and was widely grown throughout human history as a cash crop until the 1920s when various states and eventually the federal government made all forms of marijuana illegal. After years of debate, in 2014 via the federal

Farm Bill, Congress authorized state pilot programs to study the cultivation of and commercial market for industrial hemp as a viable agricultural crop. The Farm Bill's definition of industrial hemp includes any part of the plant, including the flower. Unlike the CSA, the 2014 Farm Bill distinguished industrial hemp from marijuana based on the concentration of THC contained in each species. The currently accepted legal definition of industrial hemp is any part of the cannabis plant that has no more than *0.3 percent of THC* on a dry weight basis.

Cannabis is therefore regulated by the federal government within three broad categories, including (1) marijuana regulated under the CSA, (2) exempted parts of the cannabis plant under the CSA and (3) industrial hemp under the Farm Bills. Whether CBD is classified as a controlled substance is based primarily on the part of the plant from which the CBD is derived and whether it is derived from hemp as authorized by the Farm Bill. If CBD is derived from marijuana, it falls within Schedule I of the CSA, but if it is derived from properly sourced industrial hemp, it should fall outside the CSA.

The 2018 Farm Bill

A major turning point for industrial hemp came in April 2018 with the introduction of Senate Majority Leader Mitch McConnell's Hemp Farming Act of 2018 (HFA). Senator McConnell, a hemp advocate from Kentucky, later decided that the HFA would have a better chance of passage within the 2018 Farm Bill rather than as an independent bill. A companion bill also was introduced in the House of Representatives. After approval and reconciliation by the Senate and House, the final language within the 2018 Farm Bill will make drastic changes to the current laws concerning industrial hemp. It repeals section 7606 of the Agricultural Act within the 2014 Farm Bill, which mandated that hemp be grown under the auspices of a state agricultural pilot program or institution of higher education. It also removes industrial hemp from the CSA's definition of "marijuana" and from Schedule I.

The 2018 Farm Bill should end the debate over the legal status of the plant under the CSA. All products made from industrial hemp, including CBD oil, will be legal under the CSA if they contain no more than 0.3 percent THC. State agriculture departments and Native American tribes will be free to regulate hemp in the same manner that any other agricultural commodity is regulated. The 2018 Farm Bill also should end the debate on the extent to which private businesses are allowed to engage in the commercial sales of products derived from industrial hemp, and whether hemp-derived products may be sold through interstate commerce into states that do not have industrial hemp agricultural pilot programs. The Drug Enforcement Agency (DEA) has consistently taken the position that this commercial activity was impermissible under the 2014 Farm Bill. It is hard to see how the DEA will have a legal basis to make this argument given the language of the 2018 Farm Bill.

With broad federal protections for industrial hemp−derived products to be in place soon, we turn our attention to the legality of CBD under U.S. food and drug laws.

The FDA and CBD

The U.S. Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety and efficacy of drugs and medical devices and the safety of the nation's food

supply. The FDCA forbids adulterated or misbranded food and drugs from entering into interstate commerce. It is the FDA's position that all cannabinoids, including CBD, are impermissible additives that adulterate food and supplements for both humans and animals. The FDA does not differentiate the source of CBD – whether derived from cannabis or hemp – but rather considers *all* CBD to be an illegal food ingredient, regardless of source.

Since 2015, the FDA has sent a number of letters to companies that sell CBD-infused oils and food products in interstate commerce, warning against making impermissible health claims. In the warning letters, the most recent of which is dated July 31, 2018, the FDA states that CBD products are in fact drugs, and not dietary supplements, under the FDCA because they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease and/or because they are intended to affect the structure or any function of the body. Accordingly, the "drugs" require FDA approval under the FDCA.

The FDA also concludes that CBD products are not dietary supplements under the Dietary Supplement Health and Education Act (DSHEA). Under DSHEA, dietary ingredients marketed in the United States prior to October 15, 1994, may be used in dietary supplements without notification to the FDA, but new dietary ingredients cannot be used without a new dietary ingredient notification that provides the FDA with evidence establishing that the ingredient is "reasonably expected to be safe." The FDA has concluded that CBD does not fall within the definition of a dietary ingredient because the FDA had previously authorized CBD for investigation as a new drug, for which substantial clinical research already had been conducted and made public. This is called Investigational New Drug Preclusion, or IND Preclusion. The FDA cites Epidiolex® and Sativex® as examples of clinical investigations regarding CBD that have been made public, beginning in 2006.

There has been some discussion as to whether the FDA's position on IND Preclusion may be challenged on the basis that CBD products were sold in interstate commerce prior to the publication of substantial clinical investigations of CBD. No formal challenge has been made to date, however.

Another obstacle to the legal status of CBD under FDCA is the refusal of FDA to recognize CBD as "Generally Recognized as Safe" (GRAS), which is required of all food additives. Although GRAS determination has been made in the case of hemp seed oil, the FDA concludes that further research is needed for CBD. Future GRAS applications certainly will be made for CBD, but this must be done in accordance with the scientific process and will take time.

In the meantime, the FDA has made clear that it still considers CBD unlawful in foods and supplements. In early November 2018, FDA's Director of Dietary Supplement Programs is reported to have stated at a conference that "just because we haven't taken enforcement action, people seem to think [CBD] is OK. [But] anyone who thinks it is lawful is mistaken."

Epidiolex

In June 2018, the FDA approved the first CBD-based drug, Epidiolex, for treatment of childhood seizures associated with two rare forms of epilepsy. In its June 25 press release, the FDA states:

"CBD is currently a Schedule I substance because it is a chemical component of the cannabis plant." By definition, a Schedule I substance has no accepted medical use. To resolve this conflict, in September 2018 the DEA rescheduled Epidiolex to Schedule V, the least restrictive schedule under the CSA. That action by the DEA only applies to Epidiolex and not to CBD generally.

Many commentators have argued that the FDA misses the mark by making the broad statement that CBD is a Schedule 1 substance under the CSA "because it is a chemical component of the cannabis plant." Despite conflicting statements by the DEA, the Farm Bills establish that CBD is a controlled substance only if it is derived from non-exempted parts of the marijuana plant, but it should not be a controlled substance if it is derived from industrial hemp. The Ninth Circuit has confirmed that the Farm Bills preempt and supersede the CSA.

Unfortunately for those who want to capitalize on the booming demand for hemp-derived CBD food and supplement products, this is largely a distinction without a difference and underscores the new regulatory hurdles for federal approval of cannabis- and hemp-based products. Regardless of the source of CBD, the FDA has concluded that CBD is a *drug* with a real health benefit that is used to treat certain epileptic seizures and is being investigated for other medical uses. Because the FDA has made this determination, CBD cannot be freely added to food or supplements that are sold to the public.

In sum, though the FDA's recent approval of Epidiolex has been widely viewed as a positive development by those who want to see a change to the federal scheduling of marijuana, it has unexpectedly hamstrung the fledgling market for hemp-derived CBD products that are in high demand, including when used to fight the opioid crisis.

CBD and State Regulations

Numerous states recently have weighed in on the legality of adding CBD or hemp to foods under state law. While states regulate food alongside and in cooperation with the FDA, states are responsible for food safety within state borders while the FDA's mandate is to regulate *interstate* food and drug safety. We caution, however, that regardless of whether a state has taken a specific position on the issue, all states are obligated to refrain from enacting state food and drug laws that directly conflict with FDA regulations.

California's Announcement on CBD Sets off Alarms

On July 6, 2018, in response to numerous inquiries from CBD industry stakeholders and members of the public, the California Department of Public Health (CDPH) issued a public statement that CBD sourced from industrial hemp cannot be used in food in California. The CDPH relies on the FDA's position, explaining: "California incorporates federal law regarding food additives, dietary use products, food labeling, and good manufacturing practices for food," and that the "FDA has concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added … regardless of the source of the CBD – derived from industrial hemp or cannabis."

The CDPH distinguishes CDB added to medicinal and adult-use “manufactured cannabis products,” including cannabis edibles, which are regulated by the CDPH Manufactured Cannabis Safety Branch. It explains that “although California currently allows the manufacturing and sales of cannabis products (including edibles), the use of industrial hemp as the source of CBD to be added to food products is prohibited.” Therefore, California takes the position that CBD sourced from marijuana is permitted in food products but is considered a cannabis product that only may be sold by retailers properly licensed under state cannabis regulations. On the other hand, CBD sourced from industrial hemp is *not* permitted in any food product under any condition.

California’s public statement set off alarms within the CBD and hemp industries, and it precipitated several other states to make their own statements on the issue.

Other States Weigh In
Several other states have recently clarified their respective positions on CBD under state law, though most do not distinguish between CBD that is derived from hemp versus marijuana. Many states do have exemptions under controlled substances state laws that mirror federal exemptions under the CSA.

Alabama: Guidance recently released by the state’s attorney general makes clear that “all CBD is illegal under Alabama law, except for the prescription drug Epidiolex.”

Alaska: In a September 2018 email, the state's Department of Environmental Conservation wrote "there are no lawfully approved sources of CBD" available in Alaska. As a result, the substance cannot be sold or used in permitted food establishments.

Arizona: Arizona has a medical marijuana program, but state law enforcement has interpreted the law to exclude cannabis extracts, including CBD. There is a dispute heading to the state's Supreme Court.

Colorado: Colorado’s House Bill 19-1295, which was signed into law in May 2018, modifies the Colorado Food and Drug Act to make explicit that food and drugs containing industrial hemp are not adulterated or misbranded under state law, under certain conditions.

Illinois: In late August 2018, Governor Rauner signed a bill legalizing industrial hemp. The bill legalizes the farming of industrial hemp for commercial, research or pilot programs. It also permits the use of industrial hemp in health food.

Indiana: Indiana recently has passed legislation permitting the distribution and retail sale of “low-THC hemp extract.”

Iowa: On August 17, 2018, the Iowa Department of Health issued a position statement on CBD, stating "it is the position of the Department that CBD products are not legal in the state of Iowa, with few exceptions.” One of the exceptions includes products produced and approved under Iowa's Medical Cannabidiol Act that contain less than 3% THC.

Kansas: The Kansas legislature passed a bill in June 2018 that removed from the state's controlled substances list any hemp products that do not contain THC. The industry has taken that to mean CBD oil is permitted so long as it contains zero THC.

Kentucky: The definition of marijuana under Kentucky state law exempts hemp-derived CBD products.

Michigan: The possession, purchase or sale of marijuana or any marijuana product, including CBD, must be done in compliance with the Michigan Medical Marijuana Act and Medical Marijuana Facilities Licensing Act. Any possession or transfer of industrial hemp must be done in compliance with Michigan's Industrial Hemp Research Act. The Act authorizes growing and cultivating of industrial hemp for research purposes only and does not authorize its sale or transfer.

Minnesota: Though Minnesota has little to no regulation of industrial hemp–derived CBD, the Minnesota Board of Pharmacy warns that the industry is too liberally interpreting the law. In an October 2018 article, Executive Director Cody Wiberg said, "I've sometimes characterized this as the Wild, Wild West. This is a very rapidly developing industry. There is actually very little regulation of it. The sellers will say this is a dietary supplement, the FDA has actually said no." Wiberg also said "we don't think they're legal right now," and he has urged caution among consumers.

Missouri: In September 2018, the Missouri Department of Agriculture stated that "the legality of CBD oil is currently under review," and that "we don't want to make any premature legal interpretations because of the impacts the federal Farm Bill may have."

Montana: Under Montana's Hemp Pilot Program, approved products include alcoholic beverages, including beer and distilled and infused spirits, and cannabinoid oils, including CBD for food, cosmetic and health products.

Nebraska: On November 16, 2018, the Nebraska Attorney General reminded sellers within the state that his office believes CBD is illegal. He has issued a memo to law enforcement stating that CBD remains illegal to possess, manufacture, distribute or dispense.

New York: New York has a robust industrial hemp pilot program regulated by the state's Department of Agriculture and Markets. Although the department hasn't explicitly permitted CBD-infused foods, it has a sample "CBD Research Partner Agreement" on its website that may be interpreted to imply that those licensed to grow industrial hemp can add CBD to food products.

Ohio: In August 2018, the Ohio Board of Pharmacy issued a FAQ stating that CBD oil derived from hemp has always been illegal, and that CBD is legal only when extracted and sold through the state's medical marijuana program. The FAQ cites the DEA's reasoning that cannabinoids such as CBD are found in *trace* amounts only on the exempt parts of the plant.

Tennessee: In 2014, Tennessee removed industrial hemp from the definition of marijuana in the state criminal code. In a February 2018 raid dubbed "Operation Candy Crush," deputies from Rutherford County, Tennessee, closed approximately 25 retail stores and charged the owners for selling gummies made with CBD oil. All charges were later dropped, however, on the grounds that testing by the state could not distinguish if the oil came from marijuana or industrial hemp. After Candy Crush, state officials stated that the burden of proving CBD oil is not from hemp is on the state, not the accused.

Texas: Although Texas initially considered issuing draft guidance that would bar the sale of CBD-infused products, the state has refrained from issuing guidance while it reevaluates its position.

Washington: Washington allows licensed marijuana producers to use CBD from a source not licensed by the state's Liquor and Cannabis Board, so long as the CBD product has a THC level of 0.3 percent or less on a dry weight basis and has been lab tested.

Wisconsin: In May 2018, the state issued a report concluding that the sale of CBD was illegal under state and federal law. The state Attorney General (AG) issued a statement that "law enforcement has encountered examples of products claiming to be CBD oil that resulted in people getting hurt and sick." Shortly thereafter, however, the AG backtracked and confirmed that products made from industrial hemp are lawful, including hemp-derived CBD. The AG's memo explains: "With the 2018 Farm Bill now working its way through Congress, it is likely that our current laws will be changed even further to make industrial hemp's legality clear. Therefore, I am advising law enforcement not to take enforcement action against products made from industrial hemp that is grown under a lawful hemp research pilot program, including CBD, until Congress considers changes to the law, enabling the Wisconsin State Legislature to further clarify the status of these products." Stores are currently permitted to sell CBD oil produced in compliance with state regulations.

An Absurd Result

These federal and state positions have created an absurd result. CBD now may be manufactured and distributed in many states with few restrictions but CBD may be added to food products in many states only if it is derived from marijuana. It is difficult to logically reconcile this "schizophrenic" state of the law. Although the FDA has always prohibited cannabinoids in food, it has to date only taken enforcement action when CBD products making health claims were sold online or were otherwise introduced into interstate commerce. It remains to be seen what position will be taken by the FDA when cannabis edible products are able to move in interstate commerce, thus triggering the FDA's jurisdiction.

Evaluating the Risk

Some who sell hemp-derived CBD products may be tempted to keep moving forward and hope for the best. After all, that's basically what the cannabis industry did vis-à-vis the DOJ and DEA in the face of federal illegality, and the FDA has remained largely on the sidelines when it comes to CBD because, until recently, few CBD products have been available in interstate commerce. Despite its July 2018 statement, California's Department of Public Health has not yet taken any visible enforcement action on non-cannabis CBD.

Many may therefore ask what risk there is in simply continuing to sell their products. It is tempting to focus on potential regulatory enforcement action as the greatest risk, including from recalls, seizures, injunctions and civil penalties. Tort exposure to civil lawsuits, however, is likely the larger problem. Unlike selling federally illegal cannabis products pursuant to a state-regulated market where participants are protected under state laws, no such protection exists for sellers of CBD products that are considered adulterated and misbranded under both federal and state law. Even in states that allow CBD in food products, or in states that have not yet announced a formal position, the FDA's prohibition may be enough for the determination by a jury that such products are illegally adulterated and misbranded, particularly if the CBD product is being sold in interstate commerce.

Most states have consumer protection laws that provide statutory remedies against companies that sell adulterated, mislabeled, misbranded or contaminated products. Those statutes may provide the basis for consumer class actions brought against companies that sell allegedly adulterated or misbranded food products containing CBD. Importantly, insurance companies often decline coverage for these claims, leaving the company to fend for itself. Uninsured losses arising out of similar consumer class actions have proven problematic for the dietary supplement industry for many years.

Meanwhile, class-action attorneys will be on the hunt for impermissible claims or the marketing of ingredients not approved by the FDA. Products must be labeled accurately, or they are in violation of federal and state law. Health claims must be avoided for foods and beverages that cannot claim to treat, cure or diagnose a disease. Any company that markets a dietary supplement must have adequate substantiation for any health claim made. CBD stakeholders also should be on the alert for contamination claims. Even trace amounts of THC in a hemp-derived CBD product can potentially form the basis of substantial liability, and especially if not properly disclosed on the product label.

Ultimately, the new federal protections contained in the 2018 Farm Bill will move the CBD-based food and supplement industry closer to unrestricted national and international distribution of hemp-derived CBD products. Until approved by the FDA, however, CBD as an ingredient in foods and supplements will continue to be risky. That approval process within the FDA may take months or, more likely, years. In the meantime, it is ironic that removal of the DOJ and DEA's authority over hemp-derived CBD will pave the way for the stepped-up jurisdiction and enforcement by the FDA, and a heightened risk of civil lawsuits as CBD enters the mainstream.

II. "Clarification" of Border Crossing Rules Raises More Questions for Canadian Cannabis Industry

U.S. Customs and Border Protection (CBP) clarified on October 9, 2018, that Canadians who work in Canada's legal cannabis industry may enter the United States for non-work-related reasons without negative consequences. Over the past few months, numerous individuals who are employed by the cannabis industry and, in some cases, individuals who have merely invested in the industry, have been turned away at the border and some have received lifetime bans for entry.

Statement of Clarification
CBP's clarification states in relevant part:

"A Canadian citizen working in or facilitating the proliferation of the legal marijuana industry in Canada, coming to the U.S. for reasons unrelated to the marijuana industry will generally be admissible to the U.S. However, if a traveler is found to be coming to the U.S. for reasons related to the marijuana industry, they may be deemed inadmissible."

Though this is certainly good news for Canadians traveling to the United States for personal reasons, caution must still be exercised. There are no assurances that CBP officers may be trained sufficiently to address these nuanced issues without incident. CBP agents retain discretion to reject any applicant seeking entry for reasons "related to the marijuana industry." This is a broad exception that presumably will keep border crossers at risk for any visit other than for purely personal reasons.

CBP Involvement
Indeed, the October 9 clarification emphasizes that "CBP officers are the nation's first line of defense in preventing the illegal importation of narcotics, including marijuana," and that "U.S. federal law prohibits the importation of marijuana and CBP officers will continue to enforce that law." CBP further explains that the determination of admissibility and whether possible criminal enforcement is appropriate is made by the CBP officer "based on the facts and circumstances known to the officer at the time."

Border crossers are explicitly warned:

"Generally, any arriving alien who is determined to be a drug abuser or addict, or who is convicted of, admits having committed, or admits committing, acts which constitute the essential elements of a violation of (or an attempt or conspiracy to violate) any law or regulation of a State, the United States, or a foreign country relating to a controlled substance, is inadmissible to the United States."

CBP agents will continue to look for evidence that supports the essential elements of a violation of U.S. laws relating to controlled substances. There are a number of relevant statutes and regulations in that regard. For example, to support a conviction for the crime of importation of a controlled substance (drug trafficking), the United States must establish beyond a reasonable doubt that the defendant (1) played a role in bringing a quantity of a controlled substance into the United States from outside of the country, (2) knew the substance was controlled and (3) knew the substance would enter the United States. *United States v. Moreno*, 185 F.3d 465, 471 (5th Cir. 1999). To prove aiding and abetting the importation of drugs, the United States must establish beyond a reasonable doubt that the defendant associated with the criminal venture purposefully participated in the crime and sought to make it successful. *United States v. Pando Franco*, 503 F.3d 389, 394 (5th Cir. 2007).

Despite the recent clarification by CBP, individuals involved in the Canadian cannabis industry must remain cautious when answering questions at the border about their personal

involvement in any cannabis-related business. Any questions posed by CBP must be answered truthfully at the risk of criminal prosecution. Based on the clarification, individuals who are truly entering the United States for purely personal reasons should be able to do so at little risk. Anyone who may be tempted to cross the border for business reasons and attempt to hide the truth from border agents should reconsider.

CBP officials have broad powers, and the U.S. Constitution's Fourth Amendment protections against unreasonable search and seizure are lessened at the borders. For example, CBP officials have the authority to search an individual's electronic device for a brief, reasonable period of time to perform a thorough border search. CBP also has broad access to publicly available information as well as other information from U.S. government and state government sources.

Summary

Crossing the U.S. border in the cannabis age remains potentially risky. Canadians who intend to cross the border should remain vigilant and exercise caution, notwithstanding the October 9 clarification by CBP. In fact, the clarification broadens scrutiny because CBP agents now appear to have discretion to investigate whether activity is related or unrelated to the marijuana industry. Individuals or employees of entities who believe that they may be the subject of scrutiny or review by CBP should consult with both Canadian and U.S. counsel to review their specific situation and address potential options.

III. Why State Marijuana-Impaired Driving Laws Need Reform

The expanding legalization of cannabis may be sending a message to drivers that marijuana is not as dangerous as previously thought. As noted in its July 2017 report to Congress, the National Highway Traffic Safety Administration (NHTSA) cautions that this changing perception is likely impacting personal choices regarding marijuana use, and that "as more people choose to use marijuana, it is likely more people will drive impaired by marijuana." This is borne out by recent studies that show an increasing national trend in marijuana use with a decreasing trend in alcohol use.

The number of marijuana-impaired drivers on the road will continue to increase with greater access to retail recreational cannabis and a new generation of "pot cafés" and other on-site cannabis consumption venues on the horizon in adult-use states. It is therefore critical for policy makers, insurance companies and the public to understand the risks associated with marijuana-impaired driving and the limitations in the ability of new technology to detect and prevent drugged driving.

Following is a discussion of the current scientific limitations on measuring cannabis impairment and the challenge of developing accurate and reliable roadside detection technologies. Also discussed is what research shows on the behavioral effect of marijuana on drivers, as well as the relative crash risks from marijuana-impaired driving, drunk driving and mixed alcohol/drug use. We comment on NHTSA's conclusion that currently there are no evidence-based methods to test for marijuana impairment or to differentiate the cause of driving impairment between alcohol and marijuana. We also elaborate on state driving laws and the lack of evidence that *per se* THC limits have a scientific basis. Finally, we discuss NHTSA's recommendation that before an

evidence-based solution can be developed for measuring marijuana-impaired driving, additional training, data collection and research is needed.

The Body Metabolizes Alcohol and THC Very Differently

Alcohol is readily absorbed into the bloodstream and declines at an approximately constant rate. THC concentration, however, drops rapidly at first, followed by a slower decline as lower THC levels are reached. As described in the NHTSA report, "THC is eliminated at a rate proportional to the current concentration with exponential decay." In other words, elimination occurs most rapidly when higher concentrations are present and slows down when less of the drug is present.

THC Concentration and Impairment Are Not Closely Related

Unlike alcohol consumption, where impairment closely correlates with blood alcohol concentration (BAC), the level of THC in the blood and the degree of impairment are not closely related. Peak impairment does not occur when THC concentration in the blood is at or near peak levels. In fact, studies suggest that peak impairment may occur up to 90 minutes after smoking, by which time the THC level has declined by more than 80 percent. As emphasized in the NHTSA report, peak THC level can occur at the time low impairment is measured, and high impairment may be measured when the THC level is low. In addition, a low THC level can result from recent use with some impairment, or it can result from environmental exposure or from chronic use with no recent ingestion and no impairment.

The Complex Pharmacology of Cannabis Is Not Well Understood

This difficult situation is further complicated by the complexity of cannabis. With alcohol, one ingests the identical ethanol molecule whether it's consumed in beer, wine or whisky. Cannabis, however, includes a wide variability of strains that contain dozens of cannabinoids with complex pharmacology and differing potencies and psychoactive effects that also differ depending on the method of ingestion. Most research has been based on the subject smoking cannabis; very little research has been performed on subjects ingesting edibles or using other forms of absorption such as transdermal patches or sublingual tinctures. Even the research performed to date on smoking cannabis often does not measure concentration of THC in the blood. This situation leaves the scientific community largely in the dark as to the specific causal relationship between the plant's pharmacology and impairment in the user.

Drunk Driving versus Drugged Driving

Decades of research and experience confirm that alcohol causes aggressive driving with common behaviors that include higher driving speeds, greater lane variability, lane departures and closer following distances. It is common knowledge that drunk drivers typically drive faster and take greater risks. Studies on marijuana-impaired driving, on the other hand, show that marijuana-impaired drivers typically drive slower, follow other cars at greater distances and take fewer risks than when sober. This does not mean that marijuana-impaired drivers are as safe as sober drivers, of course, because marijuana use impairs psychomotor skills, causes divided attention, and impairs lane tracking and cognitive functions. Alcohol also causes impairment in these executive functions, but alcohol causes different driving behaviors in the drunk driver compared with the drugged driver.

The relative dangers of marijuana-impaired driving compared with drunk driving are supported by empirical evidence. Studies performed on the crash risk associated with marijuana use are somewhat variable, but overall show relatively low risk estimates – or in a few cases, no risk – associated with marijuana use when compared with alcohol or mixed drug/alcohol impairment.

NHTSA's Crash Risk Study
For example, NHTSA's 2016 "Crash Risk" Study, the first large-scale study in the United States to include drugs other than alcohol, concluded that there was no increased risk of crash involvement found over sober/drug-free drivers, and that there was no difference in crash risk for drivers that had consumed both marijuana and alcohol beyond the risk attributable to alcohol alone.

DRUID Study
The large-scale European DRUID Study resulted in considerable national variability of crash risk results, with an average of 1.39 times that of drug-free drivers. This result was not considered statistically significant.

Meta-Analyses
Two recent meta-analyses, which each looked at separate groups of nine studies, found an overall pooled risk estimate of 2.66 times and 1.92 times that of drug-free drivers, respectively.

Based on the NHTSA study, the DRUID Study and the meta-analyses, it appears that the typical average increased risk of crash involvement for drivers using marijuana is up to approximately 2 times that of drug-free drivers. This compares with an increased crash risk for drunk drivers that is 5 times that of sober drivers with a BAC of 0.10, and 22 times that of sober drivers with a BAC of 0.20 (not to mention a 23-times increase in crash risk from texting while driving).

Crash Risk from Mixed Marijuana and Alcohol Impairment
The crash risk associated with the combined use of alcohol and marijuana also has been difficult to determine because of variable results from different studies. Columbia University's 2013 study showed a 23-times increase in crash risk for mixed alcohol and drug use generally, though cannabis was noted to have the least risk of the drugs studied. In a 2014 study published in the *Journal of Studies on Alcohol and Drugs*, mixed alcohol and marijuana use was not found to significantly increase crash risk beyond alcohol impairment alone. The study found that while mixed alcohol and drug use (other than marijuana) did increase crash risk to some extent, alcohol was the primary cause of crash risk. It warns:

"The lower contribution of drugs other than alcohol to crash risk relative to that of alcohol suggests caution in focusing too much on drugged driving, potentially diverting scarce resources from curbing drunk driving."

In sum, there is no compelling evidence based on a large study that marijuana use significantly increases the crash risk over alcohol impairment alone. There is consensus in the scientific community, however, that more study is needed.

Impaired Driving Detection Process

Blood testing remains the gold standard for testing the presence of alcohol and drugs in impaired driving cases. This invasive procedure, however, typically requires a search warrant that results in delay and less probative test results. In *Missouri v McNeely,* 133 S.Ct. 1552 (2013), the U.S. Supreme Court held that warrantless blood tests of alcohol concentration are not generally allowed. Warrantless breath alcohol tests are generally permissible as they are less intrusive than blood tests. See *Birchfield v. North Dakota,* 136 S.Ct. 2160 (2016).

Oral fluid testing devices are being developed, but also may require a search warrant depending on the jurisdiction. This method is minimally invasive and has been shown to be effective in detecting the presence of THC. NHTSA has concluded that devices that collect oral fluid for laboratory testing appear reliable for testing recent drug use. Roadside point-of-arrest technology, however, is still evolving and has not been shown to be completely accurate and reliable to date. Roadside oral fluid testing devices include the Alere DDS®2 Mobile Test System, which tests for five commonly abused drugs, and the Dräger DrugTest® 5000. These new devices may be used by law enforcement to provide a preliminary indication of whether a laboratory test is likely to yield a positive result for THC.

Feasibility of Developing an Impairment Standard

There currently exists no objective chemical test for marijuana impairment. As previously discussed, THC does not correlate well with impairment in any event. Very high levels of THC do indicate recent consumption, but NHTSA has pointed out that in a real-life scenario, it is unlikely that a police officer would encounter a suspect and obtain a sample of blood or oral fluid close enough to the time of consumption for high THC levels to be detected. Even if a blood test shows only low THC levels, the individual may have been quite impaired when the blood was taken. Impairment may be observed for two to three hours after smoking, whereas by one hour after smoking, peak THC levels have declined by 80 percent to 90 percent.

Without a chemical test, the alternative is to develop a subjective psychomotor, behavioral or cognitive test – something similar to the classic roadside field sobriety tests for alcohol intoxication. Available research, however, does not support the development of such tests that would be practical and feasible for law enforcement at this time. Indeed, NHTSA boldly concludes that “there are currently no evidence-based methods to detect marijuana-impaired driving.” It explains that “current knowledge about the effects of marijuana on driving is insufficient to allow specification of a simple measure of driving impairment outside of controlled conditions.”

Similarly, NHTSA concludes that there are no evidence-based methods to differentiate the cause of driving impairment between alcohol and marijuana. “These efforts will take a number of years and a successful outcome cannot be guaranteed at this time.”

Current State Laws Relating to Marijuana-Impaired Driving

It is illegal in all states to drive while impaired by alcohol or other drugs. The statutes, which have been in place for decades, require evidence that the drug *caused* the impairment. There is great variability between the states as to what constitutes “driving under the influence” (DUI).

Many states have "*per se*" laws that make it illegal to drive with more than a specific concentration of the drug in the blood or urine. For example, a number of states have adopted a *per se* limit of 2 ng/mL or 5 ng/mL for THC, and others have a zero-tolerance *per se* limit whereby any level of THC results in a violation. Only three states (California, New York and Hawaii) have a separate "driving under the influence of drugs" (DUID) statute. In all remaining states, it is a violation of the DUI law to drive under the influence of alcohol, drugs, or a combination of alcohol and drugs.

State *Per Se* THC Limits Are Not Based on Scientific Evidence

Given the poor association between the level of THC and impairment, one can see the problem with enforcement of cannabis impairment under state driving laws, all of which require the state to prove the drug caused the impairment. The NHTSA report comments on this problem, and particularly criticizes the basis of state *per se* driving laws, concluding that the "*per se* limit appears to have been based on something other than scientific evidence."

The report further explains:

"The adoption of a 5 ng/mL *per se* law for THC would appear to result in the exclusion of a large number of drivers who law enforcement officers believed to be impaired by marijuana but whose blood THC concentrations will fall below this artificial *per se* threshold during the minimum 1 to 2 or more hours it will take to collect a blood sample following a stop, investigation and arrest."

No Easy Solution

Unfortunately, there is no easy solution to the lack of an impairment standard and the conflict between current state driving laws and the determination of causation by cannabis impairment. At this time, NHTSA can only recommend increased use of effective methods to train law enforcement personnel, continued research on the development of an impairment standard, and better data collection by the states on the prevalence and effects of marijuana-impaired driving. Though all states currently participate in various levels of NHTSA courses that teach impaired-driving detection, there are only about 8,000 certified Drug Recognition Experts, the highest certification level. This number must increase to meet the challenges ahead.

Without an objective impairment standard, only those who have reached a point of demonstrating poor driving are likely to be prosecuted and convicted. This may result in many impaired drivers escaping detection, subjecting innocent drivers to increased dangers on the roadways. Until a reliable marijuana-impairment standard is developed, relevant stakeholders must continue to be educated on the unique toxicology of cannabis and how it differs from alcohol, as well as the lack of any scientific basis for state driving laws that rely on THC limits, which do not closely correlate with impairment. The public should not hold out false hope for a panacea in the form of new technology that detects and prevents marijuana-impaired driving because that technology, too, is largely premised on detecting immaterial THC levels.

IV. California Cannabis Data Security Vulnerabilities

All annual cannabis business licensees in California are required to use the California Cannabis Track and Trace METRC system, which helps regulators track cannabis throughout its life cycle and down the supply chain – from cultivator to manufacturer to distributor to lab to retailer and, eventually, to the consumer – and ensure that properly licensed cannabis doesn't end up in the wrong hands. However, to comply, business operators must maintain a large amount of valuable data, increasing the risk of liability in the event of a cybersecurity incident.

Cannabis Licensee Data Collection

The California Department of Food and Agriculture, which regulates the state's cannabis tracking system, requires that annual cannabis business licensees start using the METRC system within 15 days of licensure. The track and trace program includes an electronic seed-to-sale software tracking system that requires cannabis businesses to capture data points along the entirety of the supply chain, and record the information so that it is accessible online to regulatory authorities in real time.

Employee personnel records also must be maintained and made accessible to authorities. This includes every employee's full name, social security number or individual taxpayer identification number, and the dates of employment. Local regulations vary by jurisdiction, but often require employment applications to include employee background checks, addresses and financial account information.

Cannabis retailers are responsible for checking each customer's government-issued identification card and medical recommendation, as applicable, which may contain patient health information and medical condition. All business records must be kept for a minimum of seven years. If a business fails to maintain the requisite data, it could be subject to fines up to $30,000 per incident.

In addition to the above data, cannabis companies are beginning to employ electronic data collection to capture other operational information such as day-to-day operations management, evaluation of growth and productivity, consumer habits and information that the company submitted through the local permitting process.

Legal Implications of Data Retention

Under California law, any company that maintains specified types of data in electronic format must implement certain safeguards to ensure the security of the individual's private information. See Cal. Civ. Code §§ 1798.29, 56.101. Because the state's cannabis regulations mandate that data be available in real time, business operators are forced to support electronic data access.

More importantly, would-be hackers could wreak havoc on a business's operations given the volume and variety of data managed by cannabis businesses. For example, when software

company MJ Freeway's system was maliciously hacked in January 2017, business operations at more than 1,000 client dispensaries in 23 states across the country were interrupted. Five months later, a portion of the company's valuable source code was stolen and posted publicly on Reddit. Incidents such as these will be on the rise as the cannabis industry expands and captures the attention of malicious actors.

Risk Management Obstacles to Cannabis Data Privacy Defense

Cannabis companies preoccupied with licensing, regulatory compliance and day-to-day management might lack the time, resources or formal guidance to understand or prioritize data protection. This trend needs to be reversed, with data privacy becoming a primary risk management objective of every cannabis business.

Another major obstacle is the lack of cannabis-specific cyber or data security insurance policies available on the market. We remain optimistic, however, that as data security becomes better understood by the cannabis industry, and as insurance carriers become more comfortable operating in the cannabis space, policies that offer real cyber/data security coverage will become available. California cannabis businesses should be particularly mindful of the state's information privacy regulations and the California Confidentiality of Medical Information Act.

Minimizing Data Security Risks

One important step that a cannabis business can take to limit its exposure to litigation arising from unauthorized data disclosure is to prepare a well-designed breach response plan that identifies how and where valuable data is stored by the company, and delineates clear lines of responsibility and authority in responding to a breach. Breach response plans help to ensure that exposure is minimized at every step. Companies that understand their legal obligations will be best equipped to quickly handle the aftermath, comply with statutory disclosure deadlines and lessen the financial impact of a breach.

Cannabis companies would be wise to consider implementing additional best practices to decrease their exposure to data security threats, including:

- Not sharing passwords and using a complex password at least 12 characters in length to decrease the odds of a successful brute-force attack
- Shredding anything sensitive that is on paper
- Using a secure, private wireless network to keep out intruders seeking to "sniff" data
- Changing system passwords frequently and implementing multifactor authentication
- Training employees to identify digital security risks
- Backing up company data regularly
- Testing system security to identify vulnerabilities
- Obtaining cyber liability insurance when it becomes available for the cannabis industry.

Finally, upon becoming the victim of a breach or attack, it is critical to contact the company's IT team, legal counsel and cyber liability insurance agent immediately.

The growth of data breach litigation underscores the real and imminent exposure that cannabis operators face from both private litigants and public agencies. No risk management plan is complete without a cannabis business operator acknowledging and preparing for the risks of digital data management.

V. Moving Toward a Standard of Care for Medical Marijuana

The **Medical Board of California** has recently issued updated guidelines for physicians to avoid disciplinary action related to the recommendation of cannabis to their patients for medical purposes. The board explicitly states that these guidelines are not intended to mandate the standard of care, and that the board "recognizes that deviations from these guidelines may occur and may be appropriate depending upon the unique needs of individual patients." These guidelines, and similar guidelines by other states, however, serve as the foundation for an emerging standard of care for medical cannabis. In legal terms, the standard of care is how similarly qualified practitioners would have managed the patient's care under the same or similar circumstances. As medical cannabis becomes more widespread and accepted as a legitimate treatment by the medical community, a uniform standard is needed to ensure consistency of care and patient safety.

Along with close attention to medical documentation, essential components of the California guidelines include:

- An established physician-patient relationship
- Adequate medical evaluation
- Informed consent
- A treatment plan and ongoing monitoring.

The Physician-Patient Relationship and Patient Evaluation
The guidelines outline the key factors and considerations for assessing the appropriateness of a physician's recommendation of medical cannabis and require the establishment of a physician-patient relationship prior to the recommendation of cannabis. It is expected that the physician shall not recommend medical cannabis unless the physician is the patient's "attending physician," meaning that he or she has taken responsibility for an aspect of the medical care, treatment, diagnosis, counseling or referral of a patient. The board requires documentation of a patient's history and an initial medical examination that includes considerations such as the history of the patient's present illness, social history, past medical and surgical history, alcohol/substance abuse history, family history on addiction, psychotic disorders, mental illness, therapies with inadequate response and the diagnosis supporting a cannabis recommendation.

Qualifying Medical Conditions
Though the California Compassionate Use Act of 1996 names certain medical conditions for which cannabis may be useful (including cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis and migraine), physicians are not limited to those specific conditions. The guidelines acknowledge that there is currently "a paucity of evidence for the efficacy of cannabis in treating certain medical conditions," but that recommending cannabis for any medical condition is nevertheless "at the professional discretion of the physician acting within the

standard of care." The physician's recommendation "should be evaluated in accordance with standards of practice as they evolve over time." In an attempt to provide additional guidance on this issue to physicians, the board suggests that "the physician should base his or her determination on the results of clinical trials, if available, medical literature and reports, or on the experience of that physician or other physicians, or on credible patient reports," and that in all cases, the physician must determine that the risk–benefit ratio of cannabis is as good or better than other treatment options.

An Informed and Shared Decision-Making Process

The California guidelines emphasize the importance of an informed and shared decision-making process between the doctor and patient, which requires the physician to advise the patient on the variability and lack of standardization with cannabis. A discussion is encouraged on the use of cannabis and the varying effects it may have on different individuals. Other considerations important to the informed decision-making process are the potential cognitive effects, risks of driving under the influence, unknown risks to pregnancy or breastfeeding, and parental consent for minors.

The Treatment Plan and Medical Monitoring

The guidelines further stress the importance of a written treatment agreement for each patient that outlines the patient's individualized objectives, measurable goals and an exit strategy for discontinuing cannabis if necessary. This written treatment plan must document that the physician has advised the patient on options other than cannabis, reached a determination that the individual may benefit from cannabis, advised of the potential risks and provided an authorization for a period no greater than 12 months. The board also looks for an actual authorization, attestation or recommendation for cannabis; instructions to the patient regarding cannabis use; the results of the patient's assessment and ongoing monitoring; and a signed treatment agreement with instructions on safekeeping and the federal and state legal implications of sharing the prescribed cannabis.

Specialized Assessment for Substance Abuse and Mental Health Disorders

For any patient with a history of substance abuse disorder or a co-occurring mental health disorder, specialized assessment and treatment may be necessary. The physician is encouraged to seek consultation, as needed, with pain management, mental health or addiction specialists. The guidelines emphasize that a determination should be made that cannabis use is not masking symptoms of another condition or that cannabis use will lead to the worsening of an underlying condition.

Physician Conflicts of Interest

California's Business & Professions Code makes it unlawful for a physician who recommends cannabis for a medical purpose to accept, solicit or offer any form of remuneration from/to a facility if the physician or his/her immediate family has a financial interest in that facility. It is considered unprofessional conduct for the physician to be employed by or enter into any other agreement with any person or entity dispensing cannabis for medical purposes.

Risk Management Recommendations for Physicians

Any physician or medical group considering recommending medical cannabis to patients in California should ask several important questions, including whether there is a policy that:

- Requires a physician-patient relationship to have been established?
- Requires a medical examination of the patient?
- Requires discussion of the risks and benefits of the use of cannabis with the patient, or if the patient is a minor or without decision-making capacity, with the patient's parent or guardian?
- Requires specialized assessment and treatment for any patient who has a history of substance abuse disorder or a co-occurring mental health disorder?
- Requires maintaining adequate and accurate medical records?
- Requires that a written treatment plan be established?
- Requires a regular assessment of the patient's response to the use of cannabis and overall health and level of function?
- Prohibits the physician from recommending the medical cannabis for personal use or for use by family members?
- Prohibits the physician from being employed by, holding a financial interest in or having a professional office located at any entity or facility that dispenses cannabis for medical purposes?

Toward an Accepted Standard of Care

Other states have issued similar guidelines for physicians when determining that medical marijuana is an appropriate treatment. For example:

- Florida, New York, Washington and Ohio require physicians to complete continuing education training prior to obtaining certification to recommend cannabis.
- Oregon requires that the physician be a specialized attending physician for one of the enumerate debilitating mental conditions pursuant to Oregon Revised Statute 475B.410.
- Florida has comparable physician guidelines with regard to the written documentation requirements and specific documentation demonstrating that the medical use of marijuana likely outweighs potential health risks.
- Washington's guidelines regarding treatment plans advise physicians to include a review of other measures attempted to treat the terminal or debilitating medical condition without the medical use of marijuana, the physician's advice regarding other treatment options and a determination the patient may benefit from medical use of marijuana.

The many variations and inconsistencies among the states demonstrate the need for an accepted standard of care for physicians when considering the medical use of cannabis for patients to ensure consistency of care and patient safety. Although the various state guidelines are an important step in this process, greater uniformity is needed as medical cannabis becomes more widespread and accepted as a legitimate treatment by the medical community.