THE PATH FORWARD FOR CANNABIS

LEGAL AND REGULATORY DEVELOPMENTS IN 2019 SIGNAL CLARITY, CONFUSION FOR INSURERS

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In the ever-changing world of cannabis and regulation, it's worth taking a step back after a busy year of action in order to see where claims and litigation trends are headed in 2020 and beyond. While we are tempted to plot the 2019 passage of the Secure and Fair Enforcement Banking Act (SAFE) by the House as this year's defining moment in cannabis history, and while it is a promising needle-move, it remains just that—promising. With that in mind, let's take a look at the significant actions and developments affecting our industry this past year.

THE VAPE CRISIS: OUTBREAK OF VAPING-ASSOCIATED LUNG DISEASE

In August 2019, state health departments, the Council of State and Territorial Epidemiologists Vaping Associated Pulmonary Injury (VAPI) Epidemiology Task Force, and the Centers for Disease Control and Prevention (CDC) developed data-collection tools to monitor and track what the health care community is calling an outbreak, and what the rest of us are calling a crisis. (Both are accurate.) For those who don't know, vaping is the inhalation of a vapor that forms from liquid that has been heated in a device. As of Oct. 28, 2019, nearly 1,900 instances of vape-related lung injury had been reported to the CDC from 49 states, and 37 vape-related deaths have been confirmed.

While the CDC cautions that more tests are necessary, on Nov. 9, 2019, it announced that the outbreak of lung injury appears strongly associated with the presence of vitamin E acetate in e-cigarettes or vaping products.

From the limited data sample (1,364) analyzed on Oct. 22, 2019, the CDC reported that 86 percent of surviving patients used vapes with THC-containing products; 64 percent reported use of nicotine-containing products in the three months preceding symptom onset; 52 percent reported use of both THC-containing products and nicotine-containing products; 34 percent reported exclusive use of THC-containing products; 11 percent reported exclusive use of nicotine-containing products, and two percent of patients reported no use of either THC or nicotine-containing products.

The legislative, judicial, and business responses to the vape crisis have been as scattered as the data. Several states have issued orders banning the sale of some types of vaping devices, including Michigan, New York, Massachusetts, Rhode Island, Washington, Oregon, Montana, and Utah. (Judges in Utah and Michigan, however, have granted temporary stays on these bans, and lawsuits have been filed in other states seeking to overturn bans on vaping products.) The legal market is strongly asserting that illness and death appear linked to the use of illegal and untested black-market products. Additionally, there is concern over flavored vape products driving the demand among young people. Marketing and product restrictions are being implemented at the manufacturer and state levels.

At this time, plaintiffs seeking to sue vaping manufacturers will face difficulty proving proximate cause and the added procedural difficulty of finding and bringing in the likely foreign manufacturer of the hardware, since nearly all cartridges are sourced from factories in China. Manufacturers may be uninsured, and damages may be uncollectible. The sale of

counterfeit brands will make getting the correct party into the action a further challenge.

Surplus-lines carriers insuring cannabis manufacturers and retailers have freedom of form and can quickly revise endorsements to exclude vaping products. Admitted insurance products are predicted to stay the course of coverage, at least until causation is more reliably determined.

From a contracting perspective, resellers of hardware need to be particularly concerned with the ability of the manufacturer to extend indemnity in the event claims are associated with the hardware. Manufacturers could be expected to disclaim liability when they have no control over the composition of the liquid material heated, vaporized, and inhaled with their devices. Potential interactions between the hardware and consumables will lend to the proximate cause difficulty. The retailer that purchases the hardware and consumable from different sources may be particularly exposed on a failure-to-warn claim.

INCREASED CBD REGULATION

Another 2019 cannabis-related development is the increased regulation of cannabidiol, typically referred to as CBD. The Agriculture Improvement Act of 2018, commonly known as the "Farm Bill," legalized the production and marketing of hemp and removed hemp from the Controlled Substances Act (CSA). Hemp and marijuana are both cannabis (*Cannabis Sativa L.*) and predominantly differ in the dry weight percentage concentration of THC. There also are variations in the relative proportions of other cannabinoids and terpenes. Both hemp and marijuana are a source of CBD, one of the many cannabinoids found in cannabis. Even though hemp was removed from the CSA, Congress explicitly preserved the FDA's authority to regulate products containing cannabis or cannabis-derived compounds such as CBD under the Federal Food, Drug, and Cosmetic Act (FDCA).

The FDA has regulatory authority over drugs, dietary supplements, foods, and cosmetics. CBD can be used in cosmetics so long as it does not cause the cosmetic product to be adulterated or misbranded in any way. CBD was also approved by the FDA in June 2018 as a drug, Epidiolex, for certain rare seizure disorders. Because CBD is an active ingredient in Epidiolex, it cannot be added to foods or marketed as a dietary supplement under the FDCA, which also prohibits interstate commerce of any food that has an added drug product.

Along with the FDA, the Federal Trade Commission (FTC) has pursued enforcement actions against CBD companies. The FTC protects consumers from deceptive and unfair business practices. Here, the FTC's enforcement actions centered around deceptive advertising practices by CBD companies that were making claims unsupported by competent and reliable scientific evidence.

Together, these two federal agencies sent out a series of warning letters in March 2019 and September 2019, alleging that companies were advertising CBD products with false or unsubstantiated health claims. Further warnings stated that it was illegal to advertise CBD products as being able to "prevent, treat, or cure human disease without competent and reliable scientific evidence to support such claims."

For more risk-tolerant companies, it may be possible to avoid FDA and FTC scrutiny by marketing consumable products based on potential health benefits of CBD. No guarantees should be made on the effects of CBD, or that it will "prevent," "treat," or "cure"

ANOTHER 2019 CANNABIS-RELATED DEVELOPMENT INCLUDED THE INCREASED REGULATION OF CANNABIDIOL, TYPICALLY REFERRED TO AS CBD.

anything, and prudent manufacturers will not cite questionable experts or studies in marketing materials. Finally, it is helpful for companies to make sure their CBD products are tested for potency in reputable testing labs, and to retain records substantiating any claims.

JUDICIAL REMEDIES TO THE FEDERAL PROBLEM

Another 2019 development—and the latest sign yet that the medical benefits of marijuana have begun to attract more attention—the 2nd Circuit Court of Appeals continues to retain jurisdiction over a matter for the express purpose of compelling the Drug Enforcement Agency (DEA) to promptly review the basis upon which it has classified marijuana as a Schedule I narcotic.

For instance, the case *Washington v. Barr* involved a number of plaintiffs who claim they need to use marijuana for its medical benefits. As such, these plaintiffs alleged that the scheduling of marijuana as a Schedule I narcotic posed "a serious, life-or-death threat to their health." The trial court ruled that the plaintiffs' claims

were barred based on their failure to exhaust administrative remedies available to them prior to filing their lawsuit.

While the appellate court agreed that the plaintiffs' claims were barred due to the issue of exhaustion, the court took the unusual step of retaining jurisdiction of the matter. The three-judge panel stated that "[P]laintiffs should not be required to live indefinitely with uncertainty about their access to allegedly life-saving medication or live in fear that pursuing such medical treatment may subject them or their loved ones to devastating consequences." In retaining jurisdiction, the court pointed out that "the average delay in deciding petitions to reclassify drugs under the CSA is approximately nine years."

Going forward, the ability of the court to compel the DEA to complete an analysis of its classification of marijuana as a Schedule I narcotic might be somewhat limited. In its opinion, the court directed the DEA to "respond to plaintiffs with adequate, if deliberate, speed," while it retains jurisdiction. However, the fact remains that a federal court of appeals wants the federal government to reevaluate its classification of marijuana as a Schedule I narcotic in light of more use of the drug by thousands of Americans for its perceived medical benefits. That alone is something worth keeping an eye on, just as the court plans to do.

MEDICAL MARIJUANA AND WORKERS COMPENSATION

There is considerable variation in medical cannabis laws from state to state, including how it is prescribed, produced, and distributed; how it can be consumed; and what medical conditions it can be used to treat, resulting in many questions regarding workers compensation.

Several workers compensation court decisions have mandated reimbursement of medical marijuana by payers in states like Connecticut, New Jersey, Minnesota, Delaware, and, most recently, New York. In *Matter of WDF Inc.*, the Workers Compensation Law Judge (WCLJ) held that the use of medical marijuana to treat chronic pain is appropriate so long as the claimant files a variance request. On appeal, the full board panel, referred to as Workers Compensation Board (WCB), held that since neither the federal courts in the 2nd Circuit nor the New York Court of Appeals have found the Public Health Law invalid under federal preemption, then New York's medical marijuana law is valid and applicable law.

SEVERAL WORKERS COMPENSATION COURT DECISIONS HAVE MANDATED REIMBURSEMENT OF MEDICAL MARIJUANA BY PAYERS IN STATES LIKE CONNECTICUT, NEW JERSEY, MINNESOTA, DELAWARE, AND, MOST RECENTLY, NEW YORK.

In *Matter of Our Lady of Victory*, also in New York, the WCLJ held that reimbursement of medical marijuana was appropriate because the treating physician properly requested it to treat the claimant's chronic pain following an extensive course of conservative care. On appeal, the WCB rescinded its holding, citing that the claimant had not provided proof of eligibility to receive medical marijuana.

In another New York case, *Matter of Kellner Bros*, the employer filed for a hearing to have a claimant be weaned off opioids. The treating provider filed a medical report indicating that the claimant was, in fact, being weaned off his opioid medications, and was finding medical marijuana to be "very helpful." The WCLJ ultimately found that "medical marijuana is an appropriate medication and medically necessary," and directed the carrier to reimburse the claimant for out-of-pocket expenses for medical marijuana. On appeal, the WCB held that directing a carrier to reimburse a claimant for medical marijuana does not constitute a conspiracy to violate the Controlled Substances Act. "Here, because the WCLJ directed the carrier to reimburse the claimant, the [WCB] finds that the requirement that compliance with a directive by a tribunal does not constitute a 'voluntary' act."

With that said, there are some jurisdictions in which the courts have ruled carriers do not have to reimburse employees. In *Bourgoin v. Twin Rivers Paper Co.*, the Maine Supreme Court held that an employer cannot be ordered to reimburse an injured worker for medical marijuana because such a payment would be "aiding and abetting," a violation of federal law.

Additionally, in *Matter of Panaggio*, the New Hampshire Supreme Court held that its medical marijuana law does not prohibit a workers compensation carrier from reimbursing a claimant for the cost of reasonable and related medical marijuana. However, it remains unsettled law in the state whether a workers compensation carrier reimbursing a claimant for the cost of state-allowed medical marijuana violates federal law and, therefore, would be illegal. States with pending legislation requiring carriers to reimburse include Vermont, New Jersey, New York, Maryland, and Hawaii. ■

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