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Product and Liability Issues Facing the Growing Cannabis Industry

I. Cannabis Products Liability – Vaping/Lung Injury. One Carrier's Experience with Cannabis Products Liability Claims

As an introduction to our discussion of product liability issues facing the cannabis industry, it may be instructive to look at one insurance carrier's experience.

Topa's Experience
Topa Insurance Company is one of several carriers offering cannabis-specific insurance products. Topa developed property, liability, and products liability property forms, using a combination of standard ISO policy forms and manuscripted forms.

From the very beginning of Topa's entrance into the cannabis insurance marketplace, the threat of products liability claims and litigation generated much discussion and informed our planning regarding policy forms, exclusions, and classes of businesses to insure. We continue to believe the products liability exposure is the most difficult exposure to predict and plan for.

Carrier Perspective on Coverage
Topa offers a products liability policy to cannabis dispensaries, producers, and manufacturers as part of a package of business policies. Topa's general liability policy includes an exclusion for losses arising out of the products-completed operations hazard. Therefore, claims arising out of our insured's cannabis products would be interpreted under the products liability policy and associated endorsements.

In an attempt to anticipate and mitigate the threat of products liability claims and litigation, Topa included several exclusionary endorsements, including exclusions for injuries due to carcinogens, injuries due to specific substances (additives, pesticides, etc.) and others. Regarding vaping, Topa did not include a blanket exclusion for vaping-related injuries.

During the flurry of media coverage of vaping-related injuries in 2019, one of Topa's policyholders was named as a defendant in a products liability case. The suit alleged that plaintiff's lung injuries arose out of his use of defendants' vaping products. This case put Topa's policy forms to the test. As often happens, claims can be instructive and Topa's experience with vaping-related claims has generated several lessons.

Claims Experience

Topa has handled cannabis claims in more than a dozen states across the country. Overall, these claims are mostly property losses. A small percentage are general liability claims, such as slip and fall accidents. Topa has only seen a very small number of products liability claims and only one such lawsuit to date. Frankly, the most common appearance of products-related issues in Topa's cannabis claims experience has been on property claims, where malfunctioning grow lamps or lighting fixtures caused a fire, resulting in us pursuing subrogation claims against the manufacturer.

The vaping-related lawsuit mentioned above generated several coverage questions. Due to plaintiff's apparent long-term and willful use of the product, it is questionable whether the loss arose out of an "occurrence" (an accident) at all. It was also questionable whether the previously mentioned exclusions might apply.

II. The Genesis of Standardized Cannabis Language

The creation and revision of insurance contract language is both a science and an art. On the one hand, policy drafting requires objective research and analysis of statutory and regulatory authority, judicial precedent, and market data. On the other hand, it demands a delicate balance of anticipated enforceability, precision, and readability. There are often hundreds, if not thousands, of variables that can go into a single provision or exclusion. And with cannabis, those variables often contradict each other and can vary dramatically at the state or even Zip Code level.

Traditional standardized insurance products from advisory services (ISO, AAIS, etc.) that were not designed specifically for cannabis exposures can be incompatible with the realities of modern cannabis products and activities. Rather, creating effective cannabis insurance requires careful consideration of the unique legal history, treatment, and advancement of cannabis businesses. First, the policy drafter must review and understand applicable federal and state laws and regulations. This includes: (1) criminal, agricultural, and health statutes; (2) agency positions (DEA, FDA, USDA, etc.); (3) political climate and pending legislation; and (4) local level programs and regulations. Second, the drafter must collect and contemplate cannabis case law to predict how new or revised cannabis-specific policy language will stand up to judicial scrutiny. Finally, but equally as important, legally sufficient policy language must be made understandable and palatable for insurance regulators and policyholders.

Federal and State Laws and Regulations

The creation of any insurance language begins with an analysis of applicable legal requirements and prohibitions. Cannabis insurance is no different. If nothing else, both cannabis coverages and exclusions must somehow manage to be consistent with inconsistent federal and state laws.

While more and more states continue to legalize medicinal and recreational use, cannabis remains federally prohibited. Nevertheless, guidance from executive agencies and elected officials suggest a degree of tolerance for regulated cannabis programs. The Cole Memos, for example, formerly suggested that the Department of Justice would not interfere with cannabis businesses that followed state regulations and did not engage in specific criminal activities. Those memos were later rescinded. However, the Rohrabacher-Farr amendment remains in effect, essentially prohibiting the DOJ from spending funds to interfere with the implementation of state medical

cannabis laws. Similar internal inconsistencies can be found concerning the federal definition and scientific taxonomy of "cannabis," the FDA approval of some cannabis medications but refusal to issue concrete guidelines for CBD products, and the legalization of hemp and hemp-derived products.

Further, states that have legalized in some capacity can have very different and uniquely complicated structures for regulating their quasi-legal markets. Not every state requires robust product testing or track-and-trace systems. Some states require minimum insurance coverage, while others are silent. Creating coverage language that is definite but also flexible enough to evolve alongside of an ever-changing regulatory climate can encourage very different approaches to policy development.

Judicial Interpretation of Standardized Commercial Forms with Respect to Cannabis Exposures

Having developed an understanding of applicable statutory and regulatory law, the next step is to understand how those laws (and contract language drafted in compliance with those laws) will be interpreted in court. The federal and state court systems generally operate in sync with federal and state law, leading to reasonably predictable outcomes. But as can be the case with many complicated insurance coverage issues (e.g. pollution, surface water, insured status, reasonable and timely notice), ambiguity and public policy intervene in unanticipated ways.

There are less than a handful of instructive court decisions on the topic of cannabis insurance. While they do address issues of contract enforceability, public policy, and the knowledge and expectations of both insurers and policyholders, they also leave a lot on the table to be decided. Drafting untested policy language for an unsettled and federally illegal market means that careful and informed word choice, explicit coverage scope, and overall clarity are paramount.

When cannabis policy language is not deliberately drafted upon an informed foundation of federal law, state regulations, and judicial interpretation trends, both insurers and policyholders face unintended consequences.

III. Cannabis Vaping Litigation

Most current litigation involving vaping is brought against tobacco companies, even though cannabis companies are also allegedly implicated in the vaping epidemic. Even if black market products are at fault, legitimate companies that sold vaping products could be sued under a products liability theory because every party in the supply chain can be potentially responsible for harm caused by an allegedly defective product.

As one example, in *Wilcoxen v. Canna Brand Solutions, LLC,* the plaintiff, a police officer, initiated a lawsuit in Washington state against every entity in the cannabis supply chain, including the Chinese vaporizer battery manufacturer and distributor, the THC cartridge manufacturers, the cartridge distributor, and the retail store where he purchased the products at issue. According to the complaint, Mr. Wilcoxen purchased the vaporizer battery in January of 2018 and purchased THC cartridges from January 2018 to September of 2019, when he became ill. He alleges that he was diagnosed with pneumonia and asserts that the long-term health consequences from his injury and vaping remains unknown. The complaint asserts causes

of action for negligence and strict liability against each defendant and seeks joint and several liability.

Vaping Coverage Issues

At the threshold, to trigger insurance coverage under most commercial general liability insurance policies issued to cannabis companies, a claim must seek damages "because of" or "for" "bodily injury." As is typically seen in lawsuits asserting claims of latent injury because of long-term exposure to toxins like asbestos, anticipated vaping lawsuits might assert claims involving alleged fear of injuries that are currently undetected (or, perhaps, are not yet detectible) or that do not necessarily involve "bodily injury" as defined.

Along with the media reports of "contaminants" in vaping liquids, we foresee a rise in other vaping-related lawsuits, which may involve mislabeling of products, violation of statutes such as California's Proposition 65, or failure to warn of the presence of certain chemicals without alleging bodily injury. *Brandon Flores, et al. v. LivWell, Inc*. offers a helpful example. There, a class-action lawsuit was brought by cannabis purchasers against *LivWell*, a cannabis company. The lawsuit alleged that *LivWell* used a controversial pesticide, Eagle 20, in its marijuana. The court dismissed the lawsuit on the basis that the plaintiffs did not allege damages but sought only to recover for "mere overpayment" for the product (marijuana). Because the plaintiffs alleged no cognizable injury from their purchase of the product, the case would likely be deemed to lack the requisite bodily injury to trigger insurance under a CGL policy.

Coverage

Coverage is also typically dependent upon the requirement that the bodily injury must occur during the policy period. This requirement generates numerous coverage-related questions, including the fact-intensive question as to the timing of bodily injury, including whether various stages of alterations arising out of toxic exposure necessarily constitute bodily injury, sickness or disease.

To the extent injuries are deemed to occur during more than a single policy period, a further issue that requires analysis is the allocation of losses among several years of insurance. In many cases involving other types of toxic exposure – and again asbestos is a useful benchmark – courts have reached differing conclusions as to whether bodily injury occurs solely at the time of first exposure (or, in the case of vaping products, inhalation), whether it occurs only when the injury manifests as illness, or, alternatively, whether bodily injury is considered to have occurred continuously throughout the course of all injury, disease and/or manifest illness, in which case the bodily injury triggers all insurance policies potentially in place during the entire period.

The current spate of vaping injuries do not necessarily generate complex issues of coverage trigger, as a number of reported illness occurred within a few months of using the particular product. However, there is often a lag between the first inhalation and onset of illness. Taking the *Wilcoxen* case as an example, all insurance policies issued from the time the plaintiff first started vaping in January 2018 could be implicated. Moving beyond this particular crisis, moreover, future claims might involve long-term usage over three, four or more years – similar to traditional cigarettes.

Insurers might also attempt to limit exposure on the basis of Montrose endorsements that are already in their policies, which exclude coverage for continuing bodily injury if the injury first occurred before the applicable policy incepted. Using *Wilcoxen* as our hypothetical again, this would mean that insurers issuing policies commencing in 2019 could argue that coverage is precluded because the plaintiff started vaping a year earlier, in 2018.

Vaping Related Exclusions

Possible exclusions include general products/completed operations exclusions, health-hazard exclusions, vaping exclusions, exclusions for certain types of products (Vitamin E Acetate), public policy exclusions, illegality exclusions, and specific exclusions for psychotropic substances and cannabis. In the case of cannabis vaping, insureds would presumably argue that such exclusions are unenforceable to the extent cannabis forms an essential part of the policyholder's operations

IV. Discussions and Recent Case Law on CBD Products

In this era of a billion dollar product industry where more and more states are legalizing marijuana use, there is a significant absence of legal precedent to provide guidance on cannabis product liability issues. In fact, there have only been a handful cases dealing with cannabis product liability issues (THC and CBD combined).

CBD (cannabidiol) and THC (tetahydrocannabinol) are the most common cannabinoids found in cannabis products. THC and CBD are both marijuana and hemp. Marijuana contains much more THC than hemp (which makes it the psychoactive cannabinoid), and hemp contains more CBD (non-psychoactive and should contain less than .3 THC). THC makes you feel euphoric where CBD is linked to feelings of well-being.

To date, the FDA has only approved one CBD-based drug – Epidiolex – which is a treatment for several severe forms of rare childhood epilepsy. No other CBD or THC products have obtained FDA approval.

THC Product Liability Litigation

While each state's laws differ, the Restatement (Third) of Torts: Products Liability provides three potential claim theories: (1) defective design; (2) manufacturing flaw; and (3) inadequate instructions or warnings; (4) unreasonably dangerous and (5) misuse of a product. Additional claims we may see could include fraud, deceptive and unfair trade practices and consumer protection act claims.

The first marijuana (THC) case was a 2014 where the Denver State Fair was sued for passing around CBD edibles which actually contained THC. This has become known as the "Pot Pavilion" case. In 2015, a Colorado class action against a cannabis grower for the use of Eagle 20 pesticide which converts into cyanide when heated to a certain temperature. The third was a wrongful death matter filed in Colorado against a manufacturer and seller of THC-infused candy. Richard Kirk allegedly consumed cannabis-infused candy and killed his wife the same day. His criminal defense attorneys related his actions to his cannabis-infused intoxication. The estate sued the dispensary and edibles maker, alleging a failure to warn of the candy's potency and side effects. The THC product liability litigation are likely to include physical injury claims arising from intoxication, as well as long-term medical effects including addiction. We can also expect to see consumer suits alleging deceptive and improper marketing, such as campaigns targeting minors.

Companies selling marijuana products for medical use could also be subject to the same sorts of claims asserted against makers of conventional prescription drugs, such as failing to warn about potential side effects. Given the lack of studies conducted to date, the interaction of THC with mental health issues and other medications are unknown and are ripe for litigation.

CBD Product Liability Litigation

There has been a more robust product liability litigation surrounding CBD products. This most likely stems from the volume of CBD products sold to the general population versus only dispensaries selling THC products. Lawsuits filed against CBD manufacturers typically involved unfair practices, mislabeling of CBD content and misadvertisement on the therapeutic value of CBD products.

A few 2019 cases to highlight include a federal class action lawsuit alleging securities violations against Curaleaf. Per the FDA, Curaleaf was "illegally seeing CBD products with 'unsubstantiated claims' that the products treat cancer, Alzheimer's disease, opioid withdrawal, pain and pet anxiety."

Another matter was a lawsuit filed against JustCBD in the Southern District of Florida for overstating the quantity of CBD contained in its products. The reason for the mislabel is known and possibilities include faulty lab testing, degradation of the CBD content due to self-life or fraudulent misinformation.

The final CBD "hot topic" is CBD products failing to disclose that consumers could fail drug test by taking its products (testing positive for cannabinoids) and resulting in the loss of employment. This has been on ongoing issue as CBD products can include up to .3 THC and can remain in a person blood stream for weeks into months.

Medical Marijuana

Medical marijuana has the added challenge of a potential medical malpractice component. Product manufactures will want to be cognizant of the information that is provided not only to the consumer, but also to the consumer's physician. Warnings, instructions, and lists of side effects for patients may need to be more in depth than for recreational users. Manufacturers should also anticipate product class actions alleging that the product purchased does not provide the medical benefits proclaimed.

Schedule One designation severely limits the ability to conduct the research necessary to show the claimed benefits of cannabis products. Significant problems related to determining the appropriate dosage and potency levels for marijuana arise because cannabis remains illegal under federal law while public health science and methods are developing. Thus, there are comparatively few epidemiologic studies examining the health risks and benefits of marijuana. The industry may look for guidance from the dietary supplement industry on labeling and marketing of benefits as supplements often contain vague health benefit claims and use careful label language explaining the lack of testing or FDA approval of the claimed health benefits.

Labeling

State regulations for edible products generally establish 10 mg of THC as one "serving," and mandate that each serving be individually wrapped. However, the 10 mg standard for edibles may not be understood by some consumers. For example, is 10 mg safe for an 18-year-old but unsafe for a 65-year-old? Younger and older people metabolize substances differently. Also unknown is what level of THC in a person's system makes it unsafe to drive a car. The paucity of

science also means no baseline standards really exist for how a product should be labeled. These are scenarios which will most likely be sorted out in court.
In the meantime, companies should be sure that dosage is accurately labeled and ensure they use high-quality labs to check their products. Adequate labeling should involve explaining the concentration of THC and provide warnings against use with certain activities like driving, underage use, use in pregnancy/breastfeeding, or in use with combination of other prescriptions and non-prescription drugs. A labeling reference resource can be found at Labeling, Packaging and Product Safety – R 1000 Series & Retail Marijuana Rules and Definitions, Colorado Department of Revenue.

Child-Proof Containers
Packagers and dispensaries will want to choose the design of the products carefully and be mindful of desirability and availability to children. Child-resistant packaging standards can be found at ASTM D3475-13.

Contaminants
As mentioned above, the very first cannabis litigation was a class-action dealing with pesticide contaminants. In 2015, consumers filed a class action against LivWell, Inc. for use of fungicide Eagle 20 in its growing process which released carcinogenic hydrogen cyanide upon ignition. Flores v. LivWell Inc., No. 2015-cv-33528 (Colo. Dist. Ct. Oct. 5, 2015). The lawsuit was dismissed and there is still no guide from the EPA, FDA, or Department of Agriculture as to approved pesticides or fungicides.
Other anticipated product liability risks arise from contamination by mold and fungus. This "gray" area will be ripe for future litigation. Currently, the best guide for a prudent grower may be the regulations applied to the tobacco industry.

Vaporizers and Vape Pens
Smoking any plant has the possibility of introducing respiratory irritants. Given the temperatures involved, it is possible that the chemical substances may convert into toxic nanoparticles. The Center for Disease Control (CDC) is currently studying the national cases of sever lung injuries; even resulting in death, occurring nationwide from vaping. The CDC has identified vitamin E acetate as a chemical of concern among people with e-cigarette, or vaping, product use association lung injury (EVALID). Vitamin E acetate is used as an additive as a thickening agent in THC and e-cigarette products. However, research into the vaping epidemic is new and will require additional research.

Industry Equipment
Trimmers, extraction equipment, grow lights, and watering systems are all equipment used in the growing and production industry. Attention to safety guards, safety warnings, and handling instructions should comport with the American National Standards Institute (ANSI) safety standards to avoid potential product liability lawsuits. Additional standards are published by OSHA (federal and state), Consumer Product Safety Commission (CPSC) and Association of Equipment Manufacturers (AEM).

Litigation Timeline: When and Where is Uncertain
A timeline for when product liability litigation is expected to take off is hard to predict. When suits are filed may depend in part on when the plaintiffs' bar perceives targets with deep

enough pockets to make litigation worth the effort. This may depend on "market concentration" in the industry. For now, the industry is likely to stay dominated by smaller, regional companies, but will eventually attract larger, national and multinational players. However, most large companies will not be seriously interested in the market until marijuana is legal at the federal level.
Product liability litigation is also a function of when people start reporting injuries. Given the lack of epidemiological studies, we may not be aware of the health effects for several years down the road. The crystal ball prediction is a high volume of product liability lawsuits in the CBD arena and concentrated lawsuits surrounding THC vaping and/or edibles.

V. Potential for Harm with a Processing Facility

The legalization of cannabis and its purified products has attracted many individuals who have been involved in the industry for years, bringing with them certain attitudes and work mentalities. This attitude, slowly changing as the industry legitimizes, is to maximize profit by cutting costs and using certain marketing strategies to highlight their products. Legal requirements implemented for the general safety of the public and end user can be viewed as obstacles. Suspicion of government oversight and meddling is not uncommon.

Types of Processing, Chemicals, Inhalation, Equipment, and Poor Ventilation

Property damage, personal injury, workplace exposure, environmental impact and product labelling claims resulting from fires, explosions, hazardous material exposure, dumping of waste, and fraud have already been filed. The industry in general is prone to more of the same given the economic infrastructure, workforce personality and lack of oversight.
Processors use a variety of extraction techniques to isolate and purify the active components from the cannabis plant. THC, CBD, other cannabinoids, and terpenes represent the valuable portions of the plant. Flammable solvents such as butane and ethanol, high pressure vessels using carbon dioxide, vacuum and heating systems are all commonly employed in the refinement process. These manufacturing processes are often designed and implemented by inexperienced people who have little technical or laboratory experience.

Potential for Accidents, Property Damage, and Personal Injury

The lack of experience renders some of the operations susceptible to an increased potential for accidents such as fires, explosions, inhalation/exposure, environmental accidents and questionable quality control. Other factors which may play a role in accidents include the lack of investment capital, which make build-out difficult. Lack of design expertise can render layouts troublesome. Little formal chemistry background is common as most personnel do not have roots in traditional chemical industry. Pressure to produce with little financial leeway can force decisions which are fundamentally flawed. On top of these concerns are a lack of regulatory oversite or requirements.
Safety considerations are often the first to be dismissed. Facilities often do not contain adequate/basic fire safety equipment such as fire alarms and fire suppression capabilities. Ventilation with proper air makeup and hoods for dealing with chemical vapor containment are rare. Machinery guarding is an afterthought. To compound things even further, there are seldom safety plans, training programs or oversight for the new employees. The employee turnover in this industry is also very high, making the lack of adequate training and safety awareness a glaring issue.

Third party laboratory analysis to provide the quality control for the manufactured skews is required by law. Potency, residual solvents, pesticides, mycotoxins and heavy metals are some of the parameters which can be tested. The producer is responsible for the testing costs; therefore, it is not unreasonable to find the least expensive laboratory which can provide the necessary services; “laboratory shopping” is commonplace.
Laboratories must keep their costs down to be competitive. To do this, inexpensive/inexperienced personnel are used, and analytical shortcuts can be made to save additional overhead. Internal laboratory controls and adherence to good laboratory practices are sometimes ignored to save time and money. This has led to analytical errors and inaccurate labeling.

Currently, there is no regulatory oversight for these laboratories. There is no current program to test the accuracy/reliability of the test results from a laboratory. There are documented cases in which laboratories have falsified result to give the client what they want. Producers are susceptible to utilizing laboratories which make their products look good. Different states have different requirements for which parameters are required to be tested. Some states are now certifying cannabis/hemp testing laboratories and publish the required criteria.
All the above leads to the potential to have inaccurate labeling on cannabis packaging. Dosage information has been found to particularly problematic. Most products are silent on pesticides and heavy metals. Even the simplest line item, potency, is rarely accurate.