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# CANNABIS-INFUSED PRODUCTS: LABELLING, REGULATION AND LIABILITY

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SHOOK  
HARDY & BACON

MINI-ROUNDTABLE

# CANNABIS-INFUSED PRODUCTS: LABELLING, REGULATION AND LIABILITY



## PANEL EXPERTS

**Greg Wu**

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**Greg Wu's** practice focuses on tort and product liability defence, with an emphasis on class action and complex personal injury litigation. He has played an active role in the defence and successful resolution of class actions in several different practice areas, including product liability, environmental and employment class actions. As a member of the firm's global product liability group, he has defended cases involving a variety of products, ranging from cigarettes to windshield wipers and fire suppression systems to mortar cartridges. He has significant experience in all aspects of litigation process.

**Mike Barnett**

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**Mike Barnett's** strength lies in giving practical advice targeted to meet his clients' business goals. In his blended practice, he works with businesses and their owners to navigate challenging commercial and employment issues. Mr Barnett represents clients in disputes involving contracts, software licensing and support agreements; enterprise software implementations; restrictive covenant and trade secrets matters; unfair business practices; and product distribution and dealer issues. He routinely works with clients in the information technology, insurance, manufacturing, retail, and automotive, heavy equipment and trucking industries.

**Katie Gates Calderon**

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**Katie Gates Calderon's** practice focuses on the defence of corporations in individual and complex tort, product liability and consumer protection matters, as well as counselling tobacco, food, beverage, dietary supplement and pet food companies on matters governed by the Food and Drug Administration and US Department of Agriculture, among other regulatory schemes. As part of her litigation practice, Ms Calderon has litigated cases in state and federal courts throughout the country, including those involving asbestos products, pharmaceuticals and tobacco.

**Emily Sellers**

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**Emily Sellers** focuses her practice on class action and complex litigation matters. As a former law clerk for the Honorable Beth Phillips, US District Judge for the Western District of Missouri, Ms Sellers gained significant experience in all phases of litigation and federal practice and procedure. During law school, she completed internships with the Honorable Fernando J. Gaitan, US District Judge for the Western District of Missouri, and the US Attorney's Office for the Western District of Missouri.

**CD: How popular have cannabis-infused products become in the US? How would you characterise the growth of this market?**

**Wu:** It is safe to say that the growth of cannabis-infused products in the past few years is nothing short of extraordinary. Their popularity has become sufficiently mainstream in the US to be sold in national retail outlets despite legal uncertainty. In particular, products containing the non-psychoactive cannabinoid Cannabidiol (CBD) have primarily fuelled this growth, in the form of all manner of products, including as oils, lotions, cosmetics, tinctures, capsules, tablets and, in some states, in various food and beverages, including beer. According to a 2019 survey by Consumer Reports, an estimated 64 million Americans have tried a CBD product in the last 24 months; one in seven of their survey respondents also reported using it daily. These numbers are consistent with the financial growth predicted by cannabis market research company Brightfield Group, which predicted that CBD revenue went from about \$620m in 2018 to around \$5bn in 2019, a growth rate of 706 percent with estimated sales of \$23.7bn by 2023.

**CD: What rules and regulations currently pertain to the marketing, advertising and labelling of CBD products?**

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**Wu:** The Food, Drug and Cosmetic Act mandates certain information on product labels, including a statement of identity, statement of net weight or volume, name and address of manufacturer or distributor, warning or caution statements and ingredients. The Food and Drug Administration (FDA) also has enforcement powers over the marketing, advertising and labelling of CBD products that make therapeutic benefit or disease claims. The Federal Trade Commission (FTC) similarly prohibits marketing statements that are false or misleading. Those agencies recently sent joint warning letters to retailers of CBD products that made egregious and unsubstantiated claims on product websites and in

marketing materials, including that CBD effectively treats diseases like cancer, Alzheimer's, fibromyalgia, and psychiatric disorders. One recent warning letter also noted that one company made unsubstantiated claims regarding the calming and anti-inflammatory effects of CBD, among other things. Such claims are common on CBD labels and in marketing, and FDA and FTC's focus on these claims should be regarded as the agencies sending the industry a clear message that they are monitoring even arguably more innocuous claims like 'calming'. In addition to applicable federal law, many states now have their own laws permitting the sale of certain CBD products that may have additional labelling or registration requirements. For example, many states require CBD products to contain certain types of tracking information, such as batch or lot identification numbers, certification of independent laboratory testing, and concentration levels of CBD or other cannabinoids. For example, recent legislation in states such as Florida and Texas require CBD products sold in those states to have a scannable QR code or URL linked to a website with certification and tracking information.

### **CD: What role does the US Food and Drug Administration (FDA) play in**

### **regulating cannabis-infused products, particularly hemp-derived products?**

**Calderon:** In the 2018 Farm Bill, Congress removed cannabis with less than 3 percent tetrahydrocannabinol (THC) – commonly referred to as hemp – from the definition of marijuana in the Controlled Substances Act, but it explicitly preserved the FDA's existing authority to regulate hemp and products containing hemp-derived compounds, including CBD. The relevant FDA regulations vary depending on the type of cannabis-infused product

**"The relevant FDA regulations vary depending on the type of cannabis-infused product at issue."**

*Katie Gates Calderon,  
Shook, Hardy & Bacon*

at issue, as those products are subject to the same requirements as other FDA-regulated products. For example, cannabis or hemp-derived CBD products marketed "for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases" are considered

drugs and must be approved by the FDA before they are marketed for sale in the US. It is also unlawful under the Food, Drug and Cosmetic Act to introduce food containing added CBD into interstate commerce or to market CBD products as, or in, dietary supplements, regardless of whether the substances are hemp-derived. There are, however, some cannabis-derived food ingredients for which the FDA has completed generally recognised as safe (GRAS) evaluation notices and effectively 'approved' these ingredients for use in food, subject to some limitations, including hulled hemp seeds, hemp seed protein and hemp seed oil. Finally, with respect to cannabis-infused cosmetics, while the FDA possesses the regulatory authority to prohibit certain ingredients as adulterated – "any poisonous or deleterious substance" – at the present time, it has not determined that the presence of hemp-derived CBD renders a cosmetic product adulterated.


**CD: To what extent do concerns exist over quality metrics, such as dosage and ingredients? To what extent are such concerns leading to lawsuits being filed against CBD companies based on mislabelling and alleged deceptive marketing practices?**

**Sellers:** There are a number of concerns over quality metrics because CBD is not uniformly regulated. Under federal law, it is illegal to market

**"Despite the proliferation of the marketing and sale of CBD products, federal and state enforcement actions have been rare."**

*Emily Sellers,  
Shook, Hardy & Bacon*

CBD by adding it to a food or labelling it as a dietary supplement, and the FDA has repeatedly warned consumers of the "unknown quality" of products on the market. In this vacuum, some states have established requirements for purity. There is a wide range of state regulations and enforcement as well as in the quality of laboratory testing. For example, the Connecticut Department of Consumer Protection requires testing for THC, microbiological, mycotoxin, heavy metal and pesticide chemical residue. Despite the proliferation of the marketing and sale of CBD products, federal and state enforcement actions have been rare. In the absence of robust governmental regulation, more and more CBD companies are facing class actions regarding the




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purported quality of their product. These suits often involve claims that products were mislabelled as dietary supplements, that consumers were misled about the amounts of THC in the products or that the products were contaminated.

**CD: What are the key considerations from a risk-management perspective with cannabis products? What insurance markets are available for these products considering potentially conflicting federal and state laws and regulations?**

**Barnett:** Cannabis products, including CBD products, create, and in many instances amplify, many of the same



risks as other consumer products. Manufacturers and sellers should especially consider the use of marketing statements, especially those related to potential health benefits. Statements that suggest health benefits or the treatment of any condition drive additional risk above and beyond that associated with similar consumer products. While insurance generally will not help with egregious conduct, insurance can help defray the cost of potential claims related to product liability and marketing practices, as well as to protect directors and officers from potential liability. The mixed legality of certain cannabis products has hindered the growth of specialty insurance and has limited the effectiveness of traditional form-based insurance

coverage. However, this landscape is evolving to provide better options for cannabis operations. Cannabis-focused insurance brokers are guiding their clients to an increasing number of insurers that offer more tailored coverage options that address the current legal landscape. As an example – and a hopeful development for the future – regulators in California, Colorado and Nevada have approved the use of a businessowners policy form tailored to the cannabis industry. The increasing number of marketplace options are reducing the risk of cannabis operations and providing a meaningful pathway to insurance even without further needed government reforms. [CD](#)