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Wild West or New Frontier?

Global Cannabis Market Spurs
Legal Spend Across All Sectors



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There is no doubt that the legal landscape around cannabis-related products is confusing. Its legalization in the United States has occurred on a patchwork basis and the regulations that are emerging state-by-state have implications for manufacturers and retailers across all economic sectors, but especially for those in the food and beverage, health and wellness, and consumer product industries.

But, with one recent study by Cowen & Co. indicating that the cannabidiol (CBD) market alone could reach \$16 billion by 2025¹, the possibilities across the cannabis spectrum are great—as is the need to get a handle on the conflicting legislation making it difficult for American businesses to protect their own assets, reduce liability and take advantage of the fertile economic landscape.

Looking ahead to the evolution of this new global market, ALM conducted a survey in Spring 2019 on behalf of Shook, Hardy & Bacon to gauge where in-house counsel anticipate the greatest need for legal services pertaining to the introduction of cannabis-related products into commerce. The survey results reveal that 56% of respondents think their need for legal services in this sphere will increase over the next two years, with a significant growth in litigation threats anticipated over the next decade.



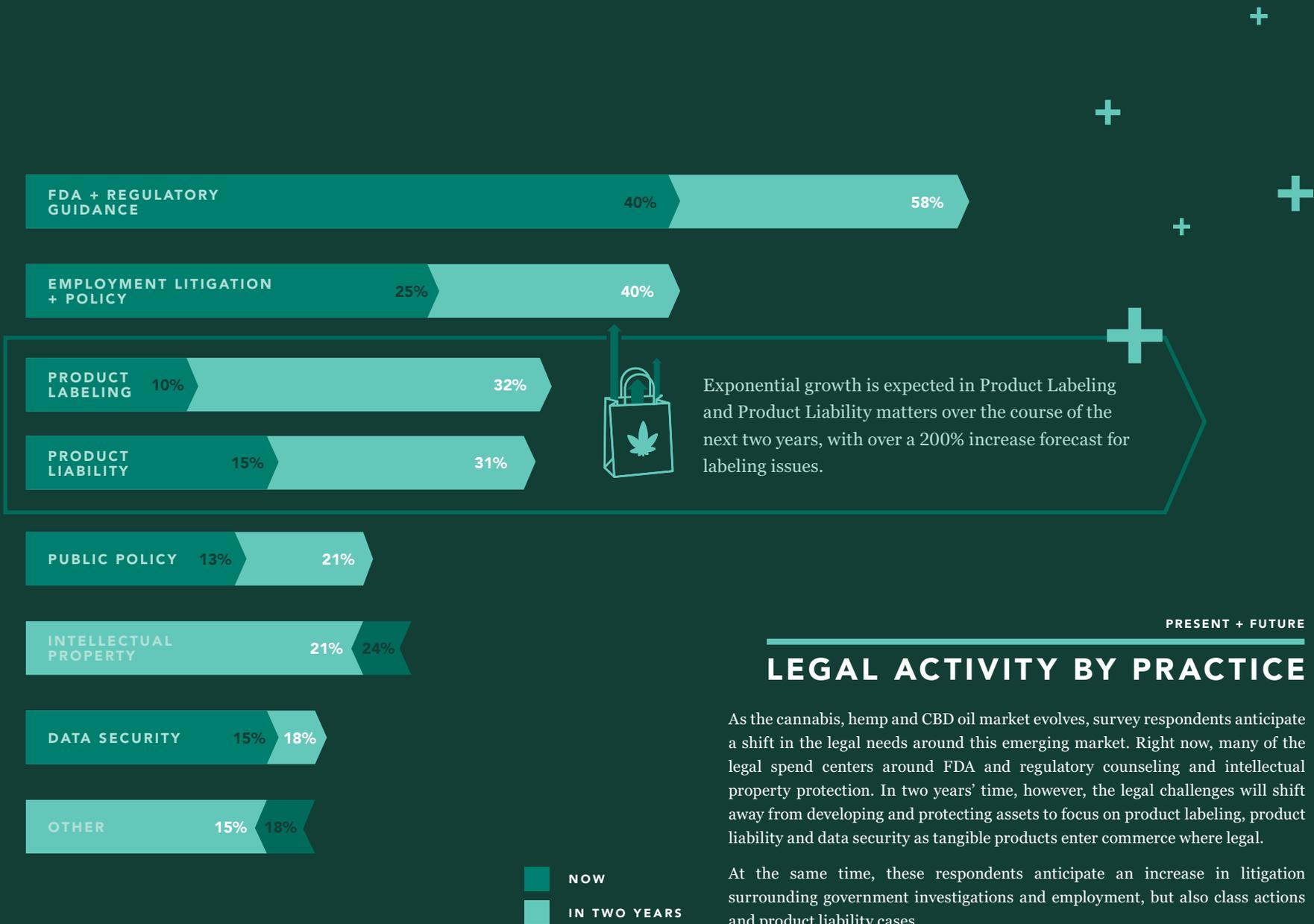
Staking a Claim: IP Gold Rush Gives Way to Liability Concerns

It's no surprise that many survey respondents—particularly those in the life science, health and wellness, and personal-care product space—are already navigating complex regulatory and employment questions around the cannabis sector, while also seeking to protect their assets and investments. But legal departments already predict that, when it comes to cannabis-related issues, the share of their legal budgets devoted to intellectual property matters will slightly decline over the next two years, even as other concerns around labeling and liability come to the fore.

In particular, Shook, Hardy & Bacon/ALM survey respondents expect increased legal spend over the next two years in the areas of Food and Drug Administration (FDA)/regulatory guidance (58%) and employment litigation and policy (40%), but also product labeling (32%) and product liability (31%). By comparison, only 15% of counsel said they are actively fielding product liability issues and only 10% are fielding labeling issues. In addi-

tion, they expect to increase their public policy work over coming years as the market matures.

“Articles and comments from industry players (and its detractors) often invoke images of the wild wild West, and that might be a fair assessment in that the legal landscape for these products remains unclear,” explains Katie Gates Calderon, co-chair of Shook, Hardy & Bacon’s Cannabis Law Practice. “The various state laws and limited federal resources to enforce, for example, FDA’s prohibition against CBD in food or dietary supplements, create confusion and have resulted in larger, more recognizable companies only reluctantly dipping their toes into the market, while smaller companies and startups with less to lose are executing cannonballs into the deep end with the optimistic view that federal regulations and state laws will ultimately catch up with consumer demands.”





Posting a Litigation Lookout: Consumer Class Actions Just Around the Bend?

Considering that the only certainty at the moment is uncertainty, it makes sense that “government investigations and enforcement” was identified by survey respondents as the primary litigation threat surrounding the introduction of industrial hemp, CBD and other cannabis products into commerce; it was chosen 33% of the time, more than twice the amount of any other response (the next highest, at 15% each, were “employment litigation” and “consumer class actions”).

“When contracting in this uncertain market, it is even more important to look around the corner and explicitly contract for a number of possibilities rather than using boilerplate,” says Shook Business Litigation Partner Mike Barnett. “It’s just as important, however, to understand there are certain risks that are part of operating in a still-developing industry. More practically, market participants should consider a level of due diligence within their supply chain to ensure the products are represented both accurately and in line with the varying and developing guidance provided from regulatory bodies. We have reviewed websites, social media and other market

representations to advise whether claims made by a business partner could potentially harm our client. We view this issue—market participants promising health benefits that are not supported by established science—as a major risk factor for the future of the industry. The work we do from due diligence through contracting may minimize this risk for our clients.”

For instance, Shook is closely tracking litigation related to the sale and transportation of industrial hemp across state lines. Even though revisions to Section 10114 of the 2018 Farm Bill state that “Nothing in this title or an amendment made by this title prohibits the interstate commerce of hemp . . . or hemp products,”ⁱⁱ the online publication *Cannabis Business Executive* reported in February 2019 that much of the excitement the Farm Bill drummed up around the possibility of interstate commerce “without interference by state and local authorities” is likely premature—and that “enforcement action against companies that distribute hemp and hemp-derived products across state lines” is most definitely occurring.ⁱⁱⁱ And, while the Department of Agriculture is

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Katie Gates Calderon

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tasked with creating the regulatory framework for state-by-state hemp programs (and laying out the interstate commerce rules for those states), states can ultimately either take it or leave it, meaning they can go with what the department recommends, create their own federally compliant program, or ban hemp production altogether.

Meanwhile, a novel issue is being tested in federal courts in Idaho and West Virginia: whether hemp-derived products can be shipped across state lines before the Department of Agriculture and states get their regulations in order, and whether CBD should be exempted from other hemp products in terms of interstate commerce.^{iv} The Idaho case, *Big Sky Scientific LLC v. Idaho State Police*, is illustrative of the gray areas that the Farm Bill introduced around industrial hemp. Big Sky is a cannabis company incorporated just days before the Farm Bill was signed, in a move that is widely seen as one that would strategically position it to take advantage of the bill's provisions. Soon afterward, a Big Sky truck carrying close to 7,000 pounds of hemp from Oregon to California to process some \$2.5 million worth of

CBD was stopped at a routine checkpoint outside of Boise, Idaho. The cargo was ultimately seized and the driver arrested and charged with felony marijuana possession (hemp and marijuana plants look and smell almost identical, and state law in Idaho doesn't distinguish between cannabis plants)^v, though the hemp was later tested and found to be below the tetrahydrocannabinol (THC) threshold of 0.3 percent as outlined by the Farm Bill.^{vi}

Big Sky sued in federal court, alleging that it was indeed transporting hemp under its federal definition—and was abiding by the transport rules outlined in Section 10114. But because Big Sky's hemp hadn't been produced in accordance with any state/USDA regulatory framework the Farm Bill outlined (the shipment was seized only weeks after its passage and no such plans were in place), the court ruled against the producer.^{vii}

The case, which will likely provide some clarity on interstate commerce rules, is currently on appeal in the Ninth Circuit. Meanwhile, the waters continue to become only muddier: Oregon is mulling interstate marijuana sales via a bill that would allow exports to other states by 2021.^{viii}



Forging Ahead: Food + Beverage Industry Readies for Foray into Cannabis Market

Those who watch and understand the industry predict a swift maturation of the market. More than 86% of in-house counsel agreed that the food and beverage industry is increasingly intersecting with the cannabis industry, a circumstance that is likely to increase demand for legal services in the immediate future.

What other legal trends are on the horizon? Among other things, Shook has seen an explosion of interest in the use of CBD ingredients in products intended for humans and animals, creating a new conundrum not just for product manufacturers but also retailers and market competitors. The 2018 Farm Bill complicated FDA's role in regulating CBD because although the substance was de-scheduled by Congress, the agency still regulates it as a drug—meaning that any consumer product with CBD is technically a misbranded drug in violation of FDA rules. While the agency has taken limited actions against companies using CBD as an additive, FDA has reiterated its authority to do so if and until regulatory changes are made.

In the first of several public hearings held by FDA on this topic, CBD proponents claimed the compound has beneficial and even therapeutic properties, including relieving pain, reducing anxiety and aiding sleep. But others suggested that the industry is rife with fraudulent marketing and potentially dangerous products contaminated with excessive levels of CBD, THC and even dextromethorphan, an active ingredient in cough syrup. Most participants agreed that FDA should step in to set a regulatory framework for the industry but differed on how this should be achieved. FDA officials posed follow-up questions to presenters that highlighted the agency's pressing concerns, including the safety data available to address dosing, drug interactions, side effects and use in special populations. While the agency is clearly taking a hard look at changing the rules for CBD, FDA did not signal if or when any regulatory changes would be implemented—which, if done under the typical time frame for FDA rulemaking, could take several years.

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And what can companies do in the meantime to stay ahead of either looming litigation threats or the shifting regulatory landscape? Survey respondents indicate that only 15% think their legal department has the right level of preparedness and can confidently navigate state and federal regulatory frameworks as they apply to cannabis-derived ingredients or products. So a first step might involve enlisting the help of outside counsel who have hands-on experience in the plethora of legal questions and consequences that arise when new and novel products are made available for public consumption.

Greg Wu, co-Chair of Shook, Hardy & Bacon's Cannabis Law Practice, explains how the firm is helping clients keep up with the ever-changing legal and regulatory framework for cannabis products and how it might affect their businesses. "We have fielded a variety of calls across a wide

swath of industries and looked at a number of interesting legal issues touching on areas ranging from product development, distribution and sale, legislative and public policy, risk management and supply chain management," he says. "These questions have been as broad as 'what types of products can be sold and in what states,' to more definite inquiries regarding analyses of proposed contractual provisions for supply chain management and indemnification."

Calderon expands: "At the end of the day, we advise our clients that whether and how to enter the cannabis market is really a matter of risk tolerance balanced against potential benefits," she says. "In other words, we can and do frequently analyze a spectrum of possible actions or products, advise our clients regarding the risk issues associated with each, and ultimately provide counsel as our clients determine the path forward for their businesses." •

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ENDNOTES

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- ii <https://docs.house.gov/billsthisweek/20181210/CRPT-115hrpt1072.pdf>
- iii “Federal Courts are Split on the Legality of Transporting Hemp and CBD in Interstate Commerce,” February 19, 2019. <https://www.cannabisbusinessexecutive.com/2019/02/federal-courts-are-split-on-the-legality-of-transporting-hemp-and-cbd-in-interstate-commerce/>
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Prepared in collaboration with ALM Media.

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ABOUT SHOOK, HARDY & BACON

Founded in 1889, Shook, Hardy & Bacon L.L.P. has 14 offices in the United States and London, with attorneys and professional staff serving clients in the health, science and technology sectors in areas ranging from product liability defense and commercial litigation to intellectual property prosecution and litigation, environmental and toxic tort, privacy and data security and regulatory counseling.

Shook's Cannabis Law Practice is conversant with the rapidly changing laws that govern the introduction of medical and recreational marijuana into more states, the addition of hemp-derived cannabidiol (CBD) consumer products into the retail space, and the de-scheduling of industrial hemp commodities that are now set to flourish in the U.S. marketplace. These new products present numerous opportunities to companies in nearly every industry; they also present challenging liability concerns at every turn—from contracting through litigation.

As a predominant international product liability powerhouse, Shook is one of the very few firms positioned to answer the needs of large national and international corporations affected by these developments. The clients who have retained us in this space include some of the largest retailers in the world, as well as pharmaceutical, consumer and personal care product, and food, beverage and alcohol manufacturers.

[Bit.ly/ShookCannabisLaw](https://bit.ly/ShookCannabisLaw)



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2019

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