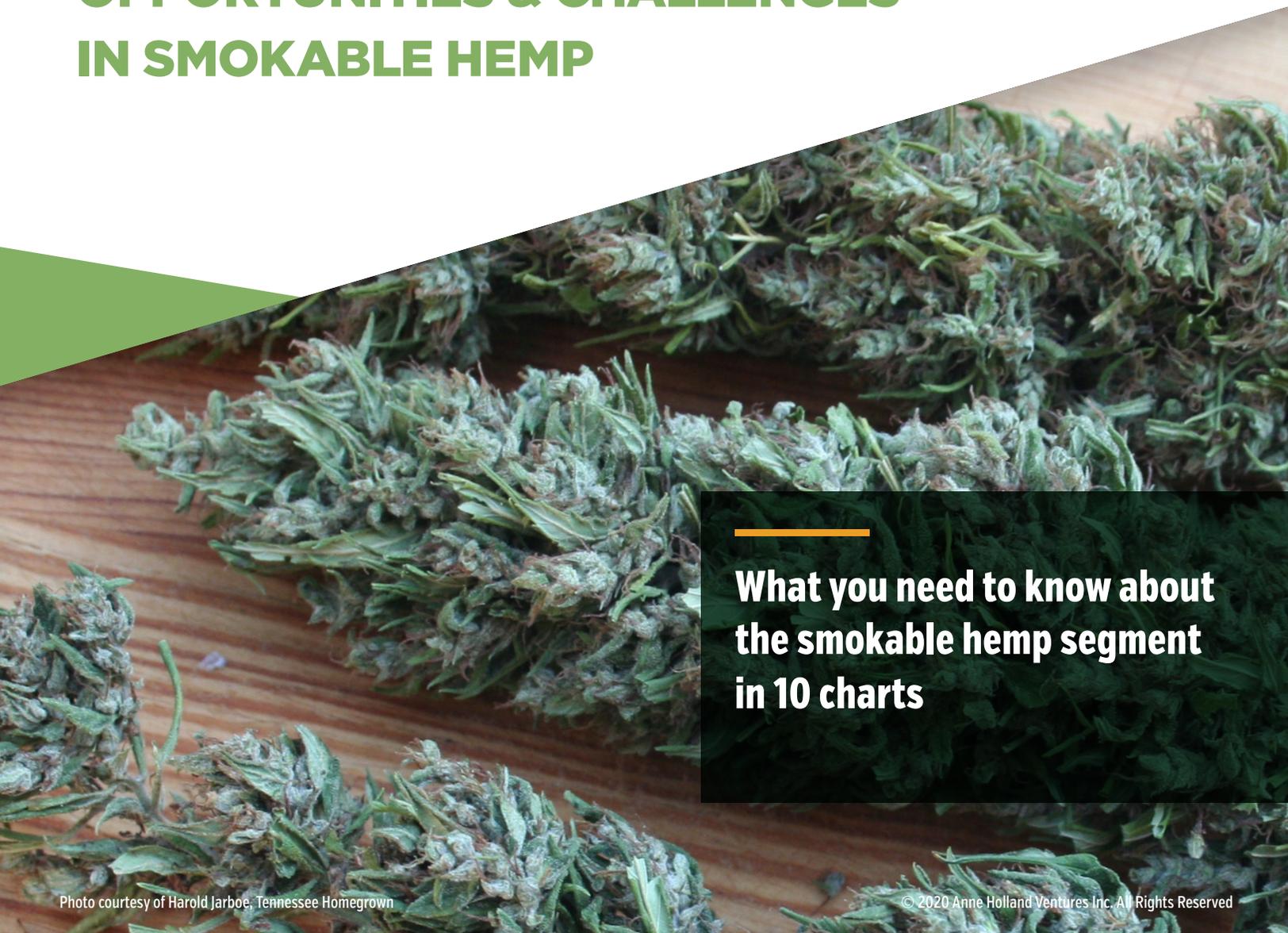


SECTOR SNAPSHOT:

OPPORTUNITIES & CHALLENGES IN SMOKABLE HEMP



What you need to know about
the smokable hemp segment
in 10 charts

Photo courtesy of Harold Jarboe, Tennessee Homegrown

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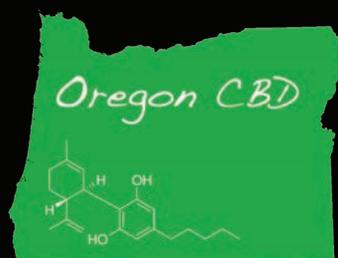
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FROM THE EDITOR



Laura Drotleff
Hemp Industry Daily

Smokable hemp is controversial. Opponents say the smokable-hemp category blurs the lines between hemp and marijuana because the two products look and smell the same. Proponents argue that smokable flower is the one area that farmers and processors are seeing profits, making typically cost-prohibitive hemp production worth the cost.

States are just as divided, with some banning all aspects of smokable hemp, from manufacture to possession, while others allow farmers and businesses to freely pursue the segment.

Despite depressed prices over the past year for biomass, farmers have recently seen prices soar for smokable flower, from \$400 to \$1,200 per pound. For many, it's the first time in years they have made money off their land.

But confusion continues around this crop. With no federal regulation and a patchwork of state laws, there are also no standard recommendations for retail, packaging and labeling. Until now, there also has been little clarity on where the market is headed, how big it's expected to grow or details about who is purchasing smokable-hemp products.

That's where this report, "Sector Snapshot: Opportunities & Challenges in Smokable Hemp," comes in.

Hemp Industry Daily has partnered with Nielsen Research to provide exclusive data on hemp and CBD retail markets and consumer purchasing behaviors around these products.

This report is a comprehensive look at the opportunities and obstacles that exist in the smokable-hemp market. Because the smokable-hemp segment is so new, most of the data available is focused on smokable-hemp flower, pre-rolls, cigarettes and cigars, specifically for CBD versus other up-and-coming cannabinoids such as CBG.

As the smokable-hemp market evolves, there will no doubt be additional areas to analyze over time.

For now, consider this a basic handbook for understanding the smokable-hemp market in the U.S., including insights on:

- The current market value for smokable hemp.
- Consumer demographics and spending analysis for smokable-hemp products.
- Comparative consumer spending on smokable-tobacco products.
- The potential market value for smokable-hemp products.
- Packaging and retail guidance.
- States that currently ban smokable hemp.
- The federal regulatory outlook.

These tools will help you assess where and how to focus your business plans in the smokable-hemp market and serve as resources to help you along the way.

If you have any questions about this report or want to provide feedback, please contact me at laura.drotleff@hempindustrydaily.com.

A handwritten signature in black ink that reads "Laura Drotleff".

Laura Drotleff
Hemp Industry Daily

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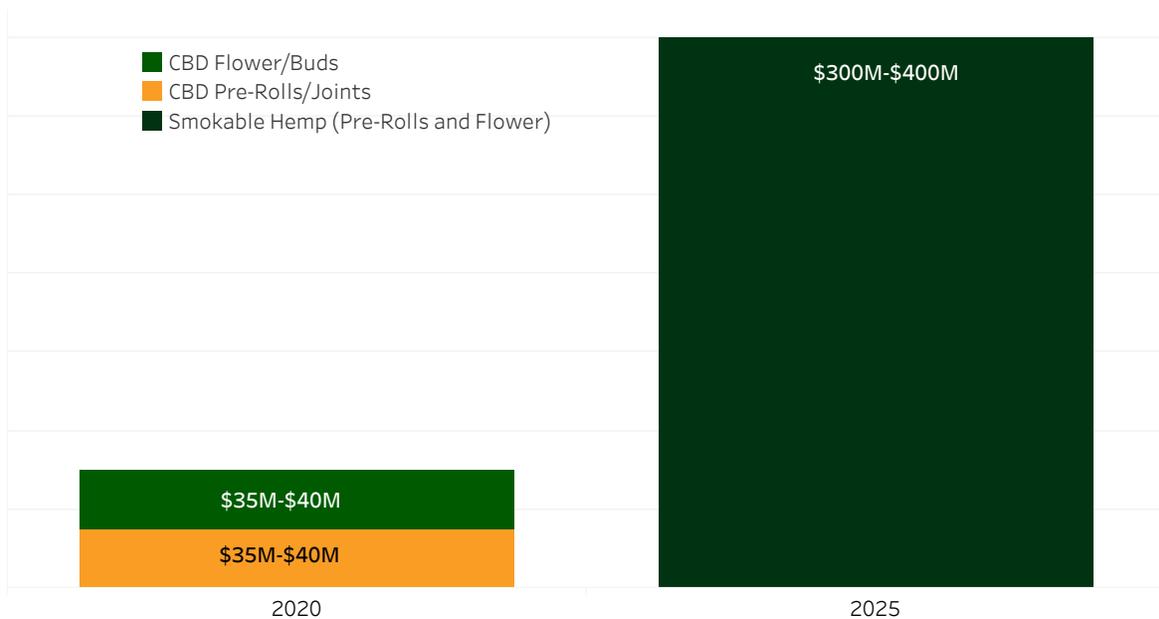
Midwest Hemp Council was formed with the goal of legalizing the commercial production of hemp and providing accurate information to ensure ease in commerce of hemp and hemp products. Following the federal legalization of commercial hemp production, MHC acts as a credible information center, a trusted policy advocate and a dedicated trade organization for the hemp industry in the Midwest and beyond. We are focused on building and promoting the hemp supply chain from seed to shelf.



www.midwesthempcouncil.com

Chart 1: Market Size Estimates for Smokable Hemp

U.S. Market Size Estimate for Smokable Hemp: 2020 vs. 2025



Source: Nielsen

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Smokable-hemp products, which include CBD flower, hemp-CBD pre-rolls, cigars and other inhalables, are part of a growing sector in the hemp-CBD market. Hemp industry observers say smokable hemp is one of the fastest-growing and most lucrative segments in the nascent hemp and CBD industry, with expectations that the market will experience fivefold growth in the next five years.

For 2020, Nielsen projects sales in the current smokable-hemp market to reach \$70 million-\$80 million. Breaking that into categories, the markets for smokable-hemp CBD flower market and for smokable-hemp-CBD pre-rolls, including hemp cigarettes and cigars, are each valued at approximately \$35 million-\$40 million.

Comparatively, total sales of all hemp-derived CBD consumer products in the U.S. were around \$1.2 billion for 2019. Nielsen projects that total sales of hemp-derived CBD consumer products in the U.S. for 2020 will be \$1.7 billion-\$2 billion. The average of that range, \$1.85 billion, would represent a 54% increase in sales from 2019 to 2020.

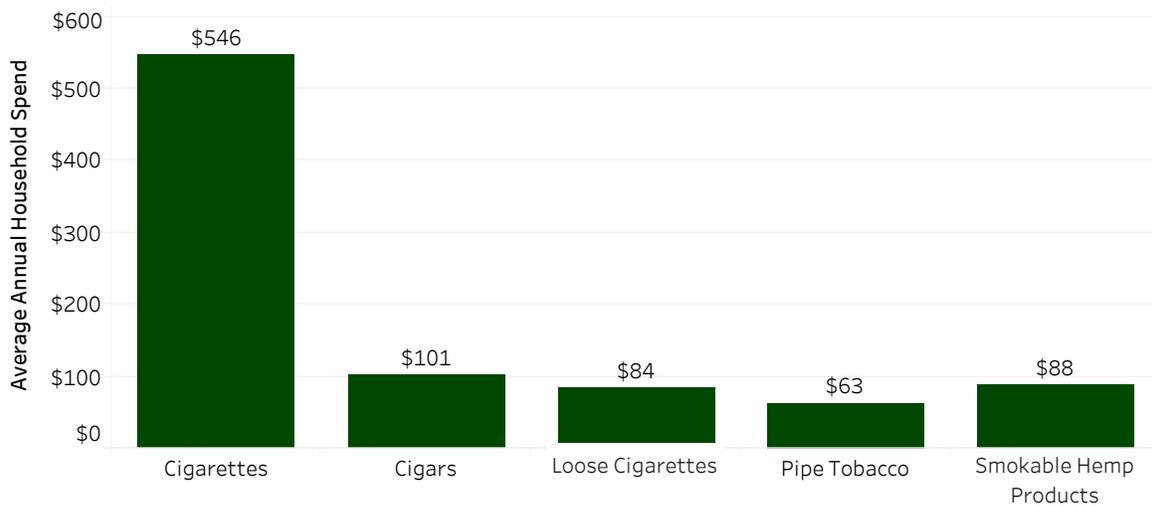
By 2025, Nielsen expects the smokable-hemp market to reach \$300 million-\$400 million, representing roughly 5% of the potential \$6 billion-\$7 billion hemp-derived CBD consumer products category.

Research shows that demand for hemp-derived CBD continues to grow, even though market projections have fluctuated based on economic factors, including disruption caused by the coronavirus pandemic, and lack of federal regulatory clarity around CBD. In fact, demand for hemp-derived CBD increased during the pandemic, likely attributable in part to growing mental-health issues from pandemic-induced anxiety and other maladies.

Smokable-hemp products, while controversial because they have a similar look and smell to other cannabis products, are said to offer faster delivery of the effects of hemp-CBD for consumers. Because of this, smokable-hemp-CBD products represent a significant share of the overall hemp-CBD market.

Chart 2: Annual Household Spend on Smokable Products

U.S. Average Annual Household Spend: Smokable Hemp vs. Tobacco Products



Annual Spending on Smokable-Hemp Products



Source: Nielsen

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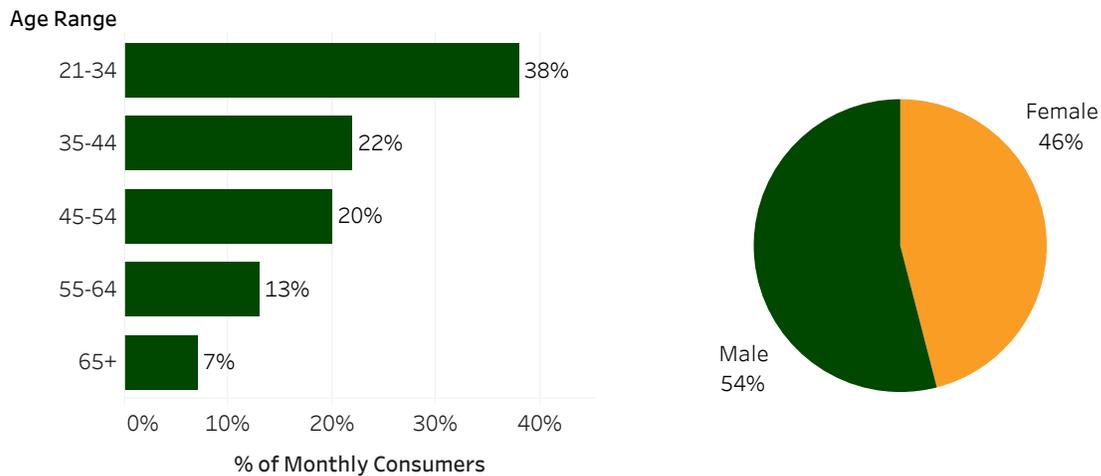
Consumers' average yearly purchases of smokable-hemp product are currently 10% of the average annual U.S. household spend for tobacco products.

While the heaviest users of hemp-CBD lay out \$300 annually, the least frequent users spend closer to \$44 per year. On average, hemp-CBD consumers spend roughly \$88 per year on smokable-hemp products.

Comparatively, consumers of smokable-hemp products outspend users of loose-pipe tobacco, who spend an average \$63 annually, and loose-cigarette tobacco, who spend \$84 per year. Meanwhile, average households spend \$101 per year on cigars and more than five times that, approximately \$546 annually, on cigarettes.

Chart 3: Smokable-Hemp Consumer Demographics

Smokable-Hemp Consumer Demographics



Source: Nielsen

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The smokable-hemp market is taking shape, and patterns are emerging among individuals and groups who are finding value in using hemp-derived CBD.

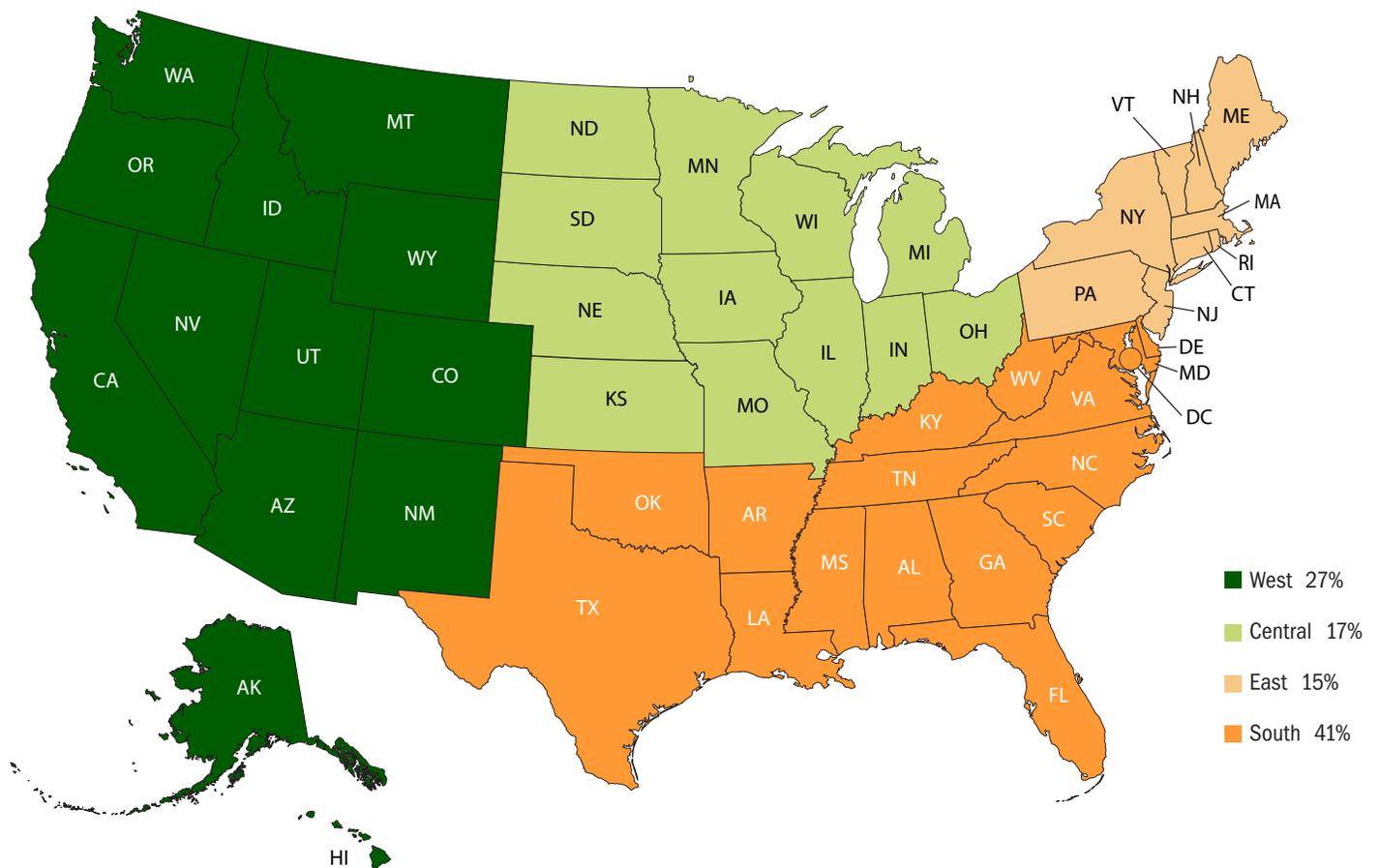
Consumers younger than 35 currently make up the largest segment (38%) of people who use smokable hemp on a monthly or more frequent basis. The next two chronological age groups, 35-44 and 45-54, make up the second- and third-largest groups, highlighting that the older consumers get, the less likely they are to use smokable hemp frequently.

While female consumers make up the larger share of general hemp-CBD consumers by a margin of 16 percentage points, those claiming to use smokable-hemp products on a monthly or more frequent basis more likely to be male, as shown in the chart above. The same is true for specific hemp-CBD products, with men reporting monthly or more frequent use of pre-rolls (56%) and flower (53%).

White consumers overwhelmingly report the most frequent usage of smokable-hemp pre-rolls and flower (76%) and hemp-CBD products in general (82%). Black consumers account for 11% of frequent smokable-hemp users and 7% of general hemp-CBD product users.

While Latin consumers represent 10% of all hemp-CBD consumers, they represent 14% of those using smokable-hemp CBD products monthly or more frequently.

Chart 4: Where Smokable Hemp Users Live (by region)



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When it comes to smokable hemp, consumer product use and spending habits are directly correlated to where they live.

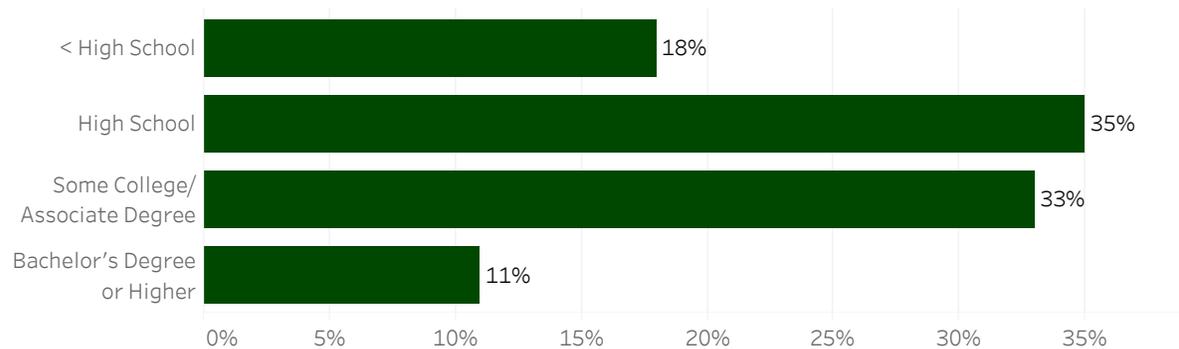
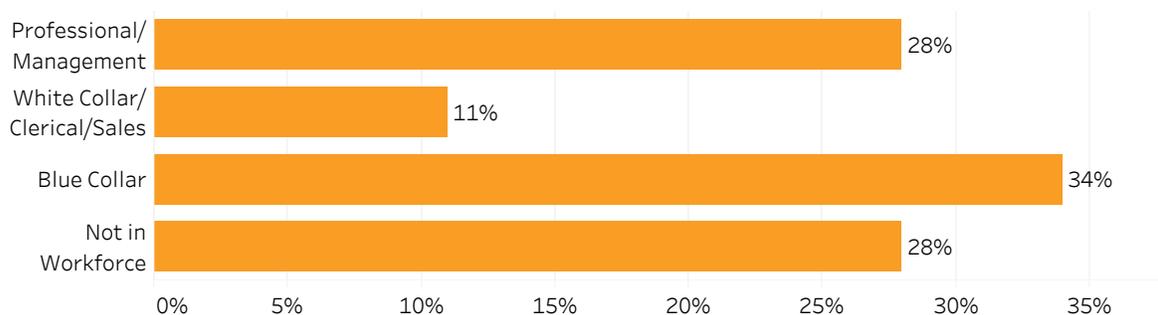
Based on demand forecasting, Nielsen noted that smokable-hemp-CBD products are in significantly higher demand in the South (41%) than in other regions of the United States.

Among those who claim to consume hemp-CBD pre-rolls monthly or more frequently, 43% reside in the South. An almost equal percentage (42%) of consumers claiming to use hemp-CBD flower at least monthly also live in the South.

These figures correspond with where adults older than 18 have a higher incidence of smoking tobacco cigarettes.

Specifically, adults in Louisiana and Mississippi are 15% more likely than those in other states to consume a smokable-hemp product if it is available. However, Louisiana is among the states that have banned the products, even going so far as to impose penalties for possession and sale of all forms of smokable hemp.

One-quarter of consumers in the West report frequent usage of smokable-hemp pre-rolls and flower as well as general hemp-derived CBD usage.

Chart 5: Education and Occupation Levels of Smokable-Hemp Consumers**Highest Level of Education Completed by Smokable-Hemp Consumers****Occupation Level of Smokable-Hemp Consumers**

Source: Nielsen

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Consumers of smokable hemp are all over the map in terms of education level and occupation.

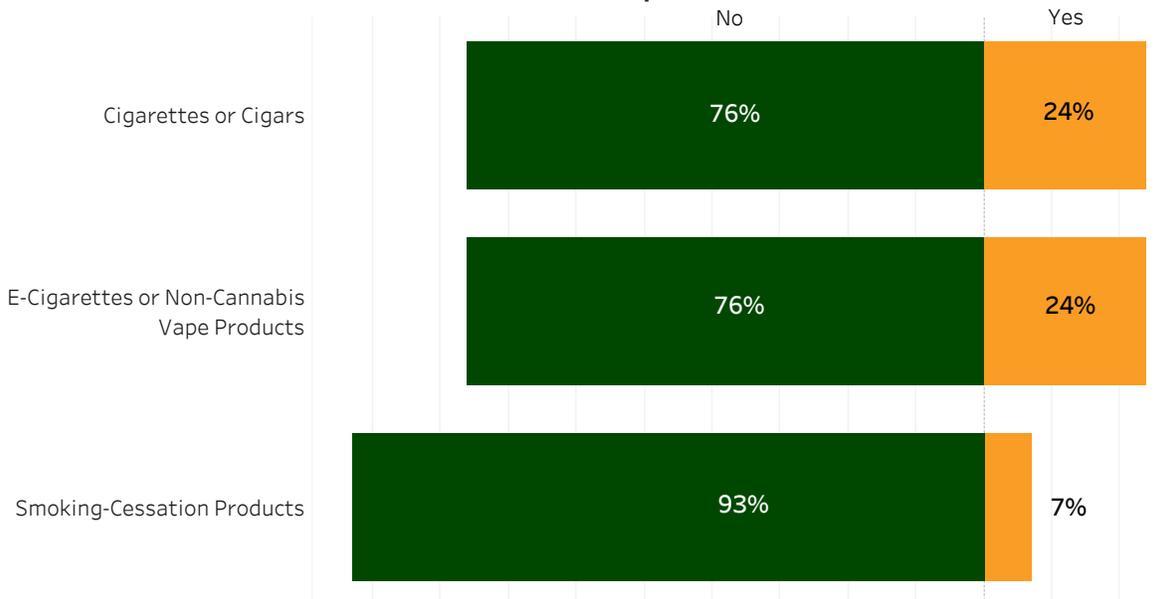
The largest cohorts of users have their high school diplomas (35%) or some level of college or associate degrees (33%). Meanwhile, consumers who have not completed high school (18%) and college graduates with bachelor's or higher-level degrees (11%) report less frequent use of both smokable-hemp products and CBD products in general.

On the career front, more blue-collar workers report using smokable-hemp products than their white-collar counterparts. However, people in professional and management roles use smokable hemp more often than those in clerical and sales positions.

Salary has little to do with consumers' reported frequency of smokable-hemp product use, with relatively even participation levels across all salary ranges.

Chart 6: Tobacco Users and Smokable Hemp

Do Tobacco Consumers Also Use Smokable-Hemp Products?



Source: Nielsen

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Retailers report some consumer product goods (CPG) migration from tobacco to hemp products—and there could be more potential for crossover to smokable hemp as tobacco use declines.

According to Nielsen, nearly 1-in-4 cigarette or cigar smokers claim to have consumed a hemp-CBD product (24%) or e-cig or non-cannabis vape product (24%). That compares to the aggregate of U.S. adults, of whom fewer than 18% have ever consumed hemp-CBD.

More specifically, 10% of tobacco cigarette/cigar smokers said they have used a hemp-CBD pre-roll or smokable flower in the past month, 8% have used a hemp-CBD pre-roll and 9% have used smokable flower.

Compared to the total U.S. adult population, cigarette and cigar smokers are 35% more likely to have ever consumed a hemp-CBD product and 157% more likely to have consumed a smokable hemp pre-roll or flower product.

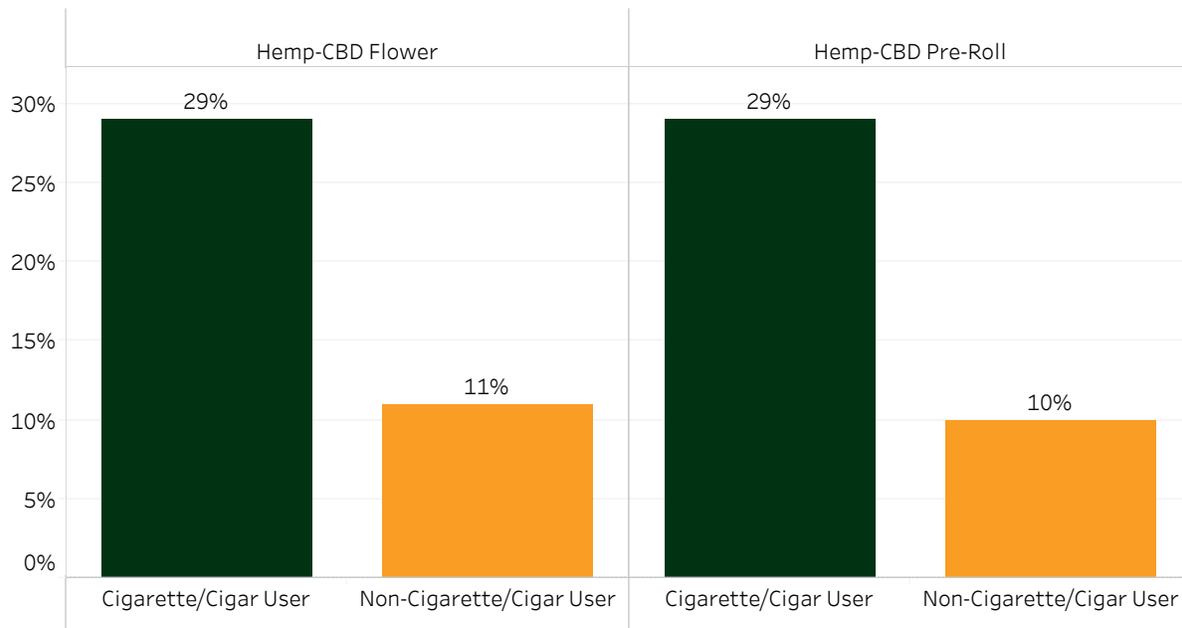
Hemp-CBD pre-rolls are more popular among tobacco users, considering that these consumers are 191% more likely to have consumed pre-rolls and 155% more likely to have consumed hemp-CBD flower in the past month.

Compared to nonsmokers, consumers who currently smoke cigarettes or cigars are 164% more likely to consume hemp-CBD flower in the next year, while 195% of smokers are more likely to consume hemp-CBD pre-roll products.

Smoking-cessation-product users are less likely (7%) to use hemp products. Hemp entrepreneurs would be wise to avoid marketing smokable-hemp or other hemp-CBD products for this use until there is more regulatory clarity around these products, as the U.S. Food And Drug Administration currently classifies smoking-cessation aids as drugs.

Chart 7: Likelihood to Consume Smokable Hemp

Likelihood to Consume Smokable Hemp in the Next 12 Months



Source: Nielsen

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Tobacco consumers in the U.S. are somewhat likely to use smokable-hemp products in the next year, with 29% of cigarette and cigar users indicating they are willing to try these products.

Compared to nonsmokers, consumers who currently smoke cigarettes or cigars are 164% more likely to consume hemp-CBD flower within the next 12 months, while tobacco smokers are 195% more likely to use hemp-CBD pre-roll products.

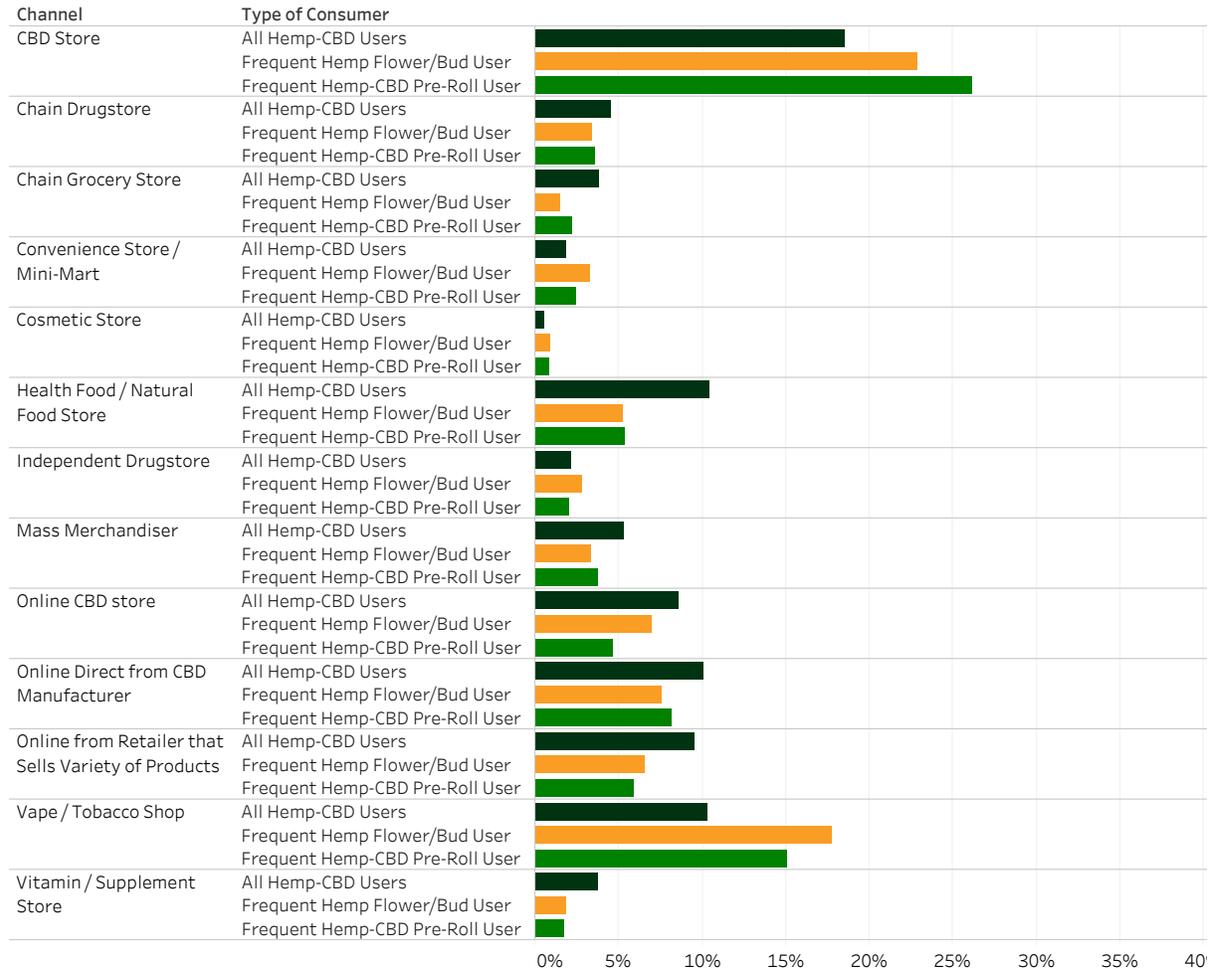
This means there is a significant opportunity to convert current tobacco users into smokable-hemp users—at least partially.

According to CannaUse, a syndicated cannabis study released in early 2020 by Nielsen, 15.8% of U.S. adults (21 or older) said they use cigarettes and 9.3% consider themselves “regular” cigarette users.

Another 11.4% said they use non-cannabis e-cigarettes or vapes, and 6% consider themselves “regular” users of these products.

Chart 8: Retail Habits: Where Consumers are Likely to Buy Hemp-CBD Products

Where Consumers are Likely to Purchase a Majority of Their Hemp-CBD Products



Source: Nielsen

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Consumers are creatures of habit, and when they find a trusted source for a favorite product, they tend to frequent that source or store unless there are dramatic and unprecedented reasons that keep them from doing so. Smokable-hemp users are no exception to this rule.

Hemp-CBD consumers and users of smokable-hemp products are currently more likely to purchase their products in a CBD specialty store than any other retail outlet. The second-highest concentration of smokable-hemp product users said they would purchase hemp flower and CBD pre-rolls in a vape or tobacco shop.

Users of both hemp-CBD pre-rolls and flower said they plan to use the same outlets—CBD specialty stores and smoke shops—as their preferred places to buy their products over the next 12 months.

However, amid the coronavirus pandemic, many states have shut down specialty retailers, including CBD shops and smoke shops, deeming them “not essential.” As a result, shop owners have had to pivot sales to online stores, and some have even closed their doors permanently because of a lack of foot traffic and repeat customers. Given that, more smokable-hemp users might turn to other channels, including convenience stores, for their hemp-CBD products.

Chart 9: Where Consumers Would Buy CBD-Hemp Products, If Available

Channels Where Consumers Would be Likely to Purchase CBD-Hemp Products, if Available



Source: Nielsen

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Hemp-CBD consumers have seen products pop up everywhere over the past year. Topicals and tinctures, for example, have appeared in mainstream retail channels such as grocery stores, convenience stores, pharmacies and malls.

Consumers indicated they would purchase CBD products, including smokable-hemp pre-rolls and flower, in these types of retail centers if the products were available there.

Should the industry receive favorable guidance from the U.S. Food and Drug Administration, minimizing the legal risk for mainstream food, drug and convenience chains to sell hemp-CBD, we anticipate that independent and specialty outlets might experience a smaller share of total sales of these smokable products.

PACKAGING TRENDS AND RETAIL RECOMMENDATIONS

Smokable-hemp product packaging is beginning to evolve based on the types of retail stores in which they're sold.

In smaller, mom-and-pop CBD specialty stores and smoke shops, it's common for retailers to sell loose-leaf flower in 1- or 2-gram containers with labels, so consumers can roll their own hemp cigarettes or put the loose-leaf flower in a pipe.

But larger retailers are beginning to gravitate away from loose-leaf smokable-hemp flower because it looks too much like marijuana, according to Jackson Garth, CEO of Atlanta-based Verde Leaf.

Verde Leaf, a vertically integrated company that contracts with farmers to produce hemp, formed a joint venture with The Alpine Hemp Group, based in Charleston, South Carolina, to place smokable-hemp cigarettes and other hemp products in up to 46,000 gas stations, convenience stores and family stores, bringing four co-branded labels to stores such as Circle K and Citgo. Verde Leaf has roughly 1,000 acres of hemp dedicated to the smokable-product joint venture.

"What big-box stores are trying to do is introduce it, because a lot of stores want to do it," Garth said. "But they're trying to have (CBD) mirror safe products, juices, drinks, cigarettes—people are cool with a cigarette."

Packaging for big-box retailers had to change, too, because retailers wanted to distance the smokable-hemp products from marijuana, Garth said.

For example, a leaf on the label might give the impression there's a psychoactive component, even if the product complies with the 0.3% THC limit, according to cannabis attorney Garrett Graff of Denver firm Hoban Law. Smokable-hemp packaging often is determined by at the discretion of law enforcement agencies, in terms of how they're going to perceive that material, as well the product manufacturer's risk tolerance.

"Loose-leaf flower versus prepackaged product is likely a higher risk, but at the end of the day, what really is the difference? Both of them will look and smell like marijuana, but really, the difference is, perhaps you're trying to mitigate the smell a little bit more by having it be prepackaged," Graff said.

Questions about product testing also arise: Was the product tested by delta-9 THC or total THC?

LABELING GUIDELINES

Because smokable-hemp products are not currently regulated at the federal level, there isn't a lot of clarity around packaging or labeling requirements, Graff noted. He said his practice will often recommend product manufacturers use best practices for other non-nicotine smokable products that are regulated by the U.S. Food and Drug Administration as a foundation for packaging and labeling guidelines.

States that have enacted smokable hemp and other CBD regulations generally also have their own labeling requirements, including QR codes and other data and information.

"In many cases, those regulations do not discriminate about the product type, meaning those same hemp-specific labeling requirements would apply to a tincture just as easily as they would apply to a smokable-hemp product," Graff said. "But there's no checklist for smokable-hemp products—in many cases, it's constructive regulation and constructive labeling requirements."

RESTRICT AT RETAIL?

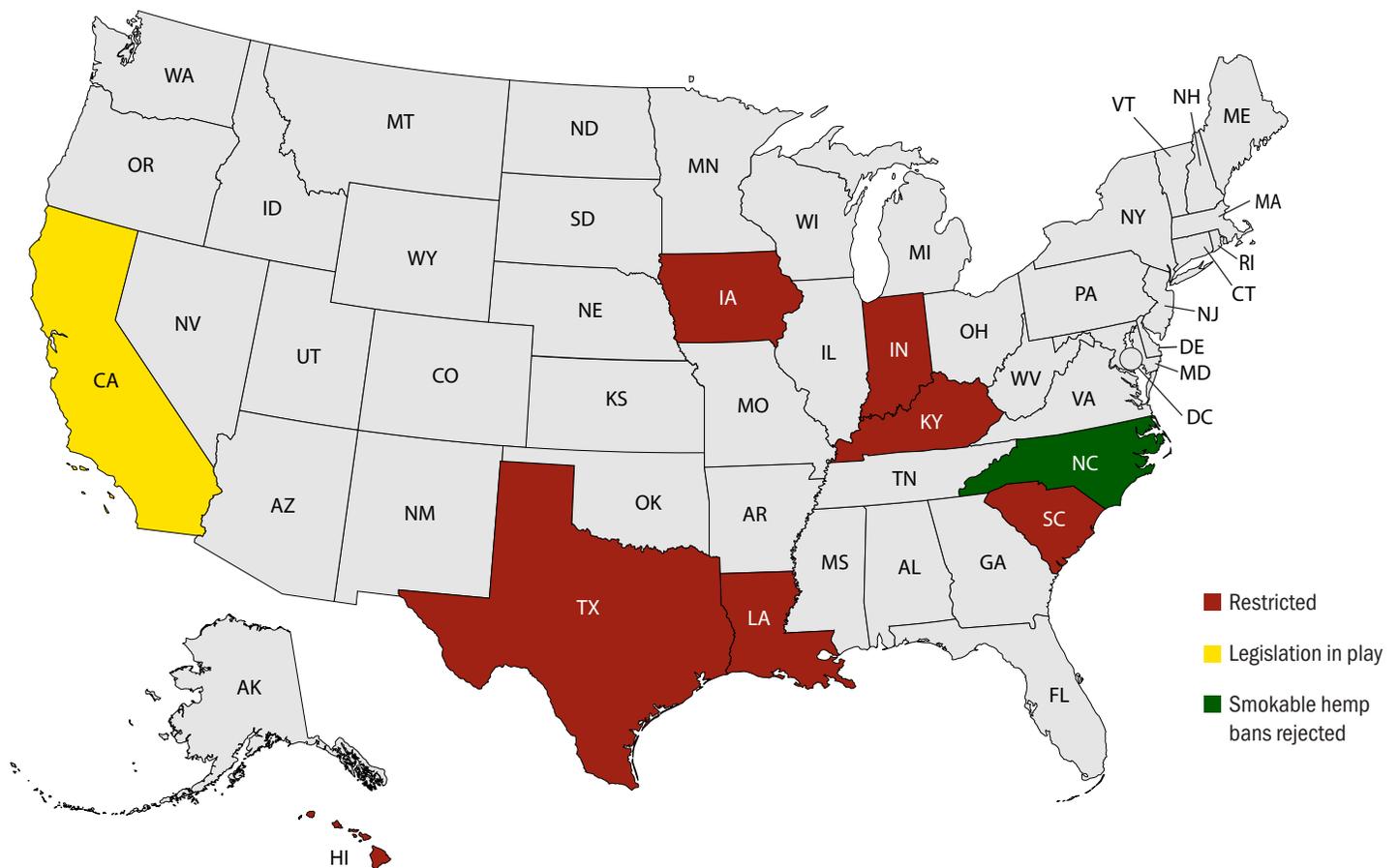
Whether it's a topical, ingestible or smokable product, cannabis attorneys recommend that hemp retailers and product manufacturers treat hemp-CBD products as restricted items in the retail setting.

Smokable products are challenging in that consistent format restrictions don't exist and product formulations can vary from state to state. A jar of loose flower could look and smell like federally illegal marijuana, sending up red flags for law enforcement, whereas packaged products are less susceptible to tampering.

Entrepreneurs could consider asking retailers to store and sell smokable-hemp products behind the counter so they can be controlled and avoid the products being sold to minors, said Jonathan Havens, a cannabis attorney with Washington DC firm Saul Ewing Arnstein & Lehr.

Putting smokable-hemp products behind the counter or behind lock and key could help manufacturers avoid legality issues involving minors purchasing products or law enforcement confiscating them; however, it could also cause the perception that smokable products need to be controlled, Graff said.

Chart 10: States Restricting Smokable or Inhalable Hemp Products



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STATE ACTIONS AGAINST SMOKABLE OR INHALABLE HEMP PRODUCTS

Smokable-hemp products remain a somewhat controversial segment of the burgeoning hemp industry, with law enforcement and officials voicing opposition across the U.S. Several states have enacted bans on smokable-hemp flower production, manufacture, distribution and sales—some of which include enforcement for possession with jail time and heavy fines.

Law enforcement in these states argue that smokable-hemp flower looks and smells too much like federally illegal marijuana, making it impossible for police to differentiate between the two products.

Meanwhile, farmers producing hemp flower for the market say that the high-demand, high-dollar crop is turning large profits, allowing them to make money on their land and making the high-input costs worth the risk.

While there are laws prohibiting smokable hemp in some states, other markets are silent about the crop and its derived products. But without explicit laws, it's still not safe for producers to assume that they can grow, manufacture, distribute and sell smokable products there, according to cannabis attorney Jonathan Havens of Washington DC firm Saul Ewing Arnstein & Lehr LLP. Entrepreneurs should check with state regulators before establishing plans to develop a business plan based on smokable hemp.

Here is a breakdown of current state actions against smokable hemp.

California

At the end of August, California state lawmakers considered a bill that would establish new hemp industry regulations. The legislation would impose strict regulation on hemp and CBD products, laying out rules for testing and the use of hemp-derived CBD in food and dietary supplements. The bill also included a ban on smokable-hemp flower and processed smokable products. Ultimately, the bill was held up in the state Senate, which means lawmakers and the industry will need to develop new proposed CBD legislation to introduce in January 2021.

Hawaii

State lawmakers approved legislation in July that aligns its hemp testing with federal law. The bill, which is awaiting Gov. David Ige's signature, bans smokable hemp, synthetic CBD and CBD-infused edibles.

Indiana

A federal appeals court ruled in July that a lower judge went too far in blocking Indiana's ban on smokable hemp. The ruling is a setback for the group of hemp companies that challenged the 2019 law, arguing that federal law guarantees interstate commerce in hemp, meaning the state could not prohibit possession of smokable hemp products passing through the state. A federal judge in Indiana sided with the hemp companies last September, putting an injunction on the law. The appeals court ruled that the overall law didn't merit an injunction, noting an exemption on transporting the product as long as the products were destined for sale outside Indiana. The case will return to a federal court in Indianapolis, which has been instructed to weigh Indiana's right to regulate hemp against language in federal law preventing states from blocking interstate commerce in hemp.

Iowa

Enactment of Iowa's Hemp Consumer and Public Safety law in June clarified that products containing CBD are legal to sell or purchase over the counter in Iowa. However, smokable hemp remains illegal in Iowa, and the new rules impose penalties and restrictions on any harvested hemp used for inhalation such as cigarettes and vaporizers. Retailers caught selling smokable-hemp products and consumers found using them could face "a serious misdemeanor" punishable by up to a year of confinement and a fine up to \$1,875.

Kentucky

Despite its heritage as a tobacco state, Kentucky in 2018 banned sales of hemp cigarettes, cigars, whole hemp buds, chew or dip containing hemp leaf or floral material, hemp leaf or floral teas and ground flowers. However, the state allows other forms of hemp CBD to be sold.

Louisiana

Louisiana rolled out penalties for the possession and sale of all smokable-hemp products, alcoholic beverages containing CBD and food and beverages containing CBD. Gov. John Bel Edwards signed the hemp limits into law in June.

North Carolina

Smokable hemp remains legal in North Carolina, at least for another year. The final measure for the state's farm bill did not include the proposed measure to phase out and ban smokable-hemp products. A majority of North Carolina hemp farmers have been producing hemp for the high-dollar smokable-hemp segment. Law enforcement argued that the look and smell of the product make it impossible to differentiate from illegal marijuana in police actions. Blake Butler, executive director of the Southeast Hemp Association, said he does not expect to see smokable-hemp bans come back up in the state after this next year; however, he said many farmers growing hemp outdoors will likely move toward producing hemp for fiber instead of CBD, while the smokable-hemp segment will move toward indoor production.

South Carolina

Law enforcement officials in South Carolina last summer began ordering retailers across the state to pull raw, unprocessed hemp products from their store shelves. The action came after an opinion handed down from the state attorney general's office interpreted language in the South Carolina Farming Act of 2019 as saying that smokable hemp falls under the definition of raw, unprocessed hemp and so cannot even be possessed without a license. However, in April, hemp companies in Georgia and South Carolina announced a joint venture to produce smokable hemp and tobacco substitutes for roughly 46,000 convenience stores.

Texas

In early August, a ban on the manufacture, processing, distribution or retail sale of consumable hemp products for smoking went into effect. The disputed measure, part of a larger hemp law signed by Gov. Greg Abbott in 2019, took effect despite thousands of hemp industry members expressing opposition. Two weeks later, a group of Texas hemp manufacturers and retailers filed a lawsuit in a state court, challenging the Texas Department of State Health Services and its commissioner, John Hellerstedt, on the recently enacted ban. The lawsuit seeks a declaration that the department's ban on processing and manufacturing hemp products for smoking in Texas is unconstitutional and that the provision banning the distribution and retail sale of hemp products is invalid, according to Chelsie Spencer, principal of Ritter Spencer in Dallas, who is representing two of the lawsuit plaintiffs. Travis County Judge Lora Livingston granted a temporary restraining order for the ban, which means that the Texas health department can't enforce it. The judge will give both sides more time to hash out the disagreement in September. The Texas dispute is the first attempt to challenge a smokable-hemp ban through state courts rather than the federal judiciary.

FEDERAL REGULATIONS LACKING

State bans on smokable-hemp products don't necessarily mean federal authorities will institute bans or restrictions on the sector, according to hemp industry insiders. But it doesn't mean federal food and drug authorities won't try to regulate them, either.

Smokable hemp flower in its raw form is most closely monitored by the U.S. Department of Agriculture. As long as crops remain compliant with the federal limit of 0.3% THC, it's unlikely the U.S. Drug Enforcement Administration will take notice of the category, cannabis industry attorneys say.

"Once the product transitions from the harvested commodity to a smokable product intended for human consumption, it would arguably transfer over to the FDA's jurisdiction," said Garrett Graff, a cannabis attorney for Denver-based Hoban Law.

Thus far, the U.S. Food and Drug Administration (FDA) has not made any policy statements or enforced any existing regulation under the Food, Drug and Cosmetics Act against smokable-hemp products, according to cannabis attorney Shawn Hauser, a partner with Denver-based law firm Vicente Sederberg.

"The FDA has cited the need to further study various methods of intake of CBD, including smoking and vaping, as a necessity in determining its ultimate regulatory approach for hemp-CBD products, indicating that it may ultimately exercise regulatory authority over these product types," Hauser said. "The FDA has also recently prioritized regulation and enforcement of e-nicotine devices."

But a federal smokable-hemp ban isn't likely anytime soon, according to Jonathan Havens, a cannabis attorney and partner with the Saul Ewing Arnstein & Lehr law firm in Washington, DC.

"In fact, even federal product restrictions could be a ways off, unless the FDA considers such products to be drugs or tobacco products," Havens said.

Down the road, the FDA will likely provide further clarity around smokable- and inhalable-hemp products, he said.

VAPE ISSUES

In light of the vape crisis of 2019, the USDA might be more concerned in the near-term future with CBD vapes than loose smokable hemp flower or derived products.

Consider:

- The FDA has tested CBD vape cartridges in its 2014-18 sampling pool, and it plans to continue to test these products.
- The FDA expressed concern in its March 2020 report to Congress that CBD vapes "pose public health risks" because vaping "raises toxicity concerns—both inherent to the substance and due to potential contaminants—and could attract children and adolescents, which are vulnerable populations."

The FDA's March report contained an entire section on vaping, suggesting the agency is thinking about the topic as broadly as possible, including regulating CBD vapes as tobacco products or, if appropriate, as drug products. More specifically, the FDA told Congress in March that, in addition to its "general public health concerns about vaping and CBD, vape products containing CBD that meet the definition of tobacco products will be regulated as such and cannot be marketed without FDA premarket authorization."

Further, the FDA said CBD-containing vape products cannot be tobacco products, will be regulated as drugs and can't be marketed with FDA-approved drug applications. The FDA said more safety data and research is needed to earn "potential implications" from the use of vape products.

"On the drug regulation front, as we have seen with ingestible CBD products, if marketers make therapeutic claims, especially aggressive ones, we might (or) could expect the FDA to take enforcement action," Havens said.

TOBACCO RULES

Meanwhile, the FDA's regulatory regime for tobacco is broad, with its definition including "any product made or derived from tobacco that is intended for human consumption." Unless smokable hemp products are mixed with tobacco or nicotine derived from tobacco, or include a component, part or accessory of a tobacco product, the tobacco definition would not apply.

However, an accessory means any product "intended or reasonably expected to be used with or for the human consumption of a tobacco product." So, if hardware, for example, isn't intended to be used with or for the consumption of tobacco, the FDA could still regulate it as a tobacco product if it's "reasonably expected" to be used for the same purposes.

Given the broad definition of tobacco products and the FDA's clear indication that "CBD-containing vape products meeting the definition of tobacco products will be regulated as such," it is possible the FDA could take action against such products absent the agency's premarket authorization, which is not easy or inexpensive to achieve.

"To the extent a marketer is selling a CBD vaping product that can only be used for that purpose, for example, it's not a cartridge-based system in which a CBD cartridge could be swapped out for an e-liquid cartridge, the FDA would have a hard time arguing it's a tobacco product," Havens said.

The FDA could still decide to take an interest in smokable hemp if they think the products will be attractive to minors.

SMOKING CESSATION

Entrepreneurs in the smokable hemp space should be careful not to make claims about their products in marketing collateral, such as positioning them as smoking cessation products.

"To the extent a smokable product was deemed to violate drug provisions or tobacco provisions, the FDA still has the authority to regulate that," Havens said.

There are two ways that the FDA has talked about regulating smokable or inhalable products:

- As a tobacco product.
- As a therapeutic or drug product.

But FDA regulates smoking-cessation aids as drug products, Havens said.

"So if you're making smoking-cessation claims and to the extent you don't have approval from the FDA to market it as such, which I imagine, folks who are making those claims with CBD or hemp products don't," he said. "Then, yes, you might expect that the FDA would say you're marketing an unapproved drug product."

GROWING THE SMOKABLE-HEMP MARKET

The smokable-hemp category faces the challenge of generating organic-user growth. Although it's not too far-fetched to think that someone who isn't using functional gummies today might take up CBD-infused gummies, it's more difficult to get someone who is a nonsmoker to take up smoking. It's a polarizing action—and one that is still largely perceived to be harmful.

Some say smokable hemp must first be regulated and normalized. New consumers might be more likely to buy a product in a form they recognize, such as a cigarette, as long as it's proven to be safe and the benefits to the product can be communicated.

Currently, because they are not federally regulated, smokable-hemp-CBD and other CBD brands are explicitly prohibited from marketing their products with unproven medical claims. Making such claims will result in a warning letter, or worse, from the U.S. Food and Drug Administration. However, many consumers are using the products for those purposes already.

For example, data from Nielsen indicates that 28% of those likely to consume a hemp-CBD product say they will use it “to reduce or replace my usage of tobacco and nicotine products.” Of those who already consume hemp-CBD products, one in 10 say they use it for nicotine cessation.

Cannabis, in general, also has tremendous overlap with nicotine usage. U.S. adults who claim to smoke cigarettes or cigars are 48% more likely than the average U.S. adult to have consumed a hemp-CBD product. Those who claim to use a nicotine-infused vape or e-cigarette are 75% more likely to have consumed a hemp-CBD product.

Brands can continue to call out that their products are “nicotine-free,” but they must wait for more U.S.-sponsored clinical research to come out supporting CBD as a cessation aid.

As the number of cigarette smokers continues to fall each year and new smokers continue to diminish, this is not a long-term, viable strategy. More specifically, smokable-hemp-CBD formats will likely face increased competition from cigarette smokers who migrate to vaporable forms that do not necessitate any combustion and are generally considered to be a safer alternative.

Other research shows that CBD can help those who suffer from “cannabis use disorder,” which is estimated to afflict 8% to 11% of marijuana users. Smokable hemp could be a viable alternative.

While health claims are off limits in marketing, identification of consumer cohorts for targeted messaging is not. Just use caution with the type of messaging to avoid specific health claims.

COMPETITION WITH MARIJUANA

By 2025, Nielsen projects, the smokable-hemp market will achieve between \$300 million to \$400 million in total sales, a 20% increase over its current value.

However, with potential recreational marijuana legalization on the horizon in the U.S., the market for smokable hemp products has some caveats.

Nielsen estimates that 75% of the U.S. adult population will have legal access to marijuana-derived products by 2025. This could lead to increased competition between legal marijuana-derived products and hemp-derived CBD products, especially given that CBD-dominant marijuana has become more popular.

More than half (52%) of U.S. adults who are likely to consume any cannabinoid-containing product, including hemp-CBD, CBD-dominant marijuana and THC-dominant marijuana, indicate they are likely to consider all three types of products.