

Vermont Cannabis Control Board

DRAFT Report to the General Assembly
Pursuant to Section 9 of Act 158 (2022)

January 15, 2023



Overview

- **Background and Requirements**
- **Key Findings and Recommendations**
- **National Overview**
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Background and Requirements

- Requirements of the Report
- Existing CCB Authority over Consumable Hemp Products

Requirements of the Report: Act 158 (2022), Section 9

On or before January 15, 2023, the Cannabis Control Board shall submit to the House Committees on Agriculture and Forestry and on Ways and Means and the Senate Committees on Agriculture and on Finance written recommendations on how the Cannabis Control Board would regulate hemp products, as that term is defined in 7 V.S.A. § 861; hemp processors; and hemp product manufacturers. The recommendations shall include:

- (1) what hemp products the Cannabis Control Board would regulate;
- (2) how the products would be regulated, including whether registration would be required and whether hemp processors and manufacturers should be licensed and regulated by the Board;
- (3) any registration fees or other charges that would be assessed on hemp products and license fees assessed on hemp processors and manufacturers; and
- (4) the resources required to regulate hemp processors, product manufacturers, and hemp products.

Existing CCB Authority over Consumable Hemp Products

Act 158 (2022), Section 3:

"(a) The Board shall adopt rules to implement and administer this chapter in accordance with subdivisions (1)-(7) of this subsection. (1) Rules concerning any cannabis establishment shall include: ... (S) requirements for cannabis control testing of hemp, hemp-infused products, cannabis, and cannabis products."

Act 158 (2022), Section 4:

"The Cannabis Control Board shall establish a cannabis quality control program for the following purposes: (1) to develop potency and contaminant testing protocols for hemp, hemp-infused products, cannabis, and cannabis products; (2) to verify cannabinoid label guarantees of hemp, hemp-infused products, cannabis, and cannabis products; (3) to test for pesticides, solvents, heavy metals, mycotoxins, and bacterial and fungal contaminants in hemp, hemp-infused products, cannabis, and cannabis products; and (4) to certify testing laboratories that can offer the services in subdivisions (2) and (3) of this subsection."

Act 158 (2022), Section 9:

"(a) On or before January 15, 2023, the Cannabis Control Board shall submit to the House Committees on Agriculture and Forestry and on Ways and Means and the Senate Committees on Agriculture and on Finance written recommendations on how the Cannabis Control Board would regulate hemp products, as that term is defined in 7 V.S.A. § 861; hemp processors; and hemp product manufacturers. The recommendations shall include: (1) what hemp products the Cannabis Control Board would regulate; (2) how the products would be regulated, including whether registration would be required and whether hemp processors and manufacturers should be licensed and regulated by the Board; (3) any registration fees or other charges that would be assessed on hemp products and license fees assessed on hemp processors and manufacturers; and (4) the resources required to regulate hemp processors, product manufacturers, and hemp products."

Existing CCB Authority over Consumable Hemp Products (Cont.)

Act 158 (2022), Section 10:

"The Board shall have the authority to regulate synthetic cannabinoids and hemp-derived cannabinoids, including delta-8 and delta-10 tetrahydrocannabinol."

Act 158 (2022), Section 12:

"(a) The Board shall adopt rules to implement and administer this chapter in accordance with subdivisions (1)–(7) of this subsection. (1) Rules concerning any cannabis establishment shall include: ... (I) regulation of additives to cannabis and cannabis products, including those cannabidiol derived from hemp and substances that are toxic or designed to make the product more addictive, more appealing to persons under 21 years of age, or to mislead consumers; ... (5) Rules concerning retailers shall include: (C) requirements that if the retailer sells hemp or hemp products, the hemp and hemp products are clearly labeled as such;"

Key Findings and Recommendations

- **Consumable Hemp Products – Key Facts**
- **Outline of Recommended Regulatory Structure – Cannabis Market Products**
- **Outline of Recommended Regulatory Structure – General Retail Products**

Consumable Hemp Products – Key Facts

- The 2018 Farm Bill exempted hemp from the Controlled Substances Act (CSA) but expressly preserved the FDA's authority to regulate hemp and products containing hemp ingredients under the Food, Drug, and Cosmetic Act (FDCA), as well as other product safety laws and regulations.
- Thus far, only a few hemp-derived ingredients like hemp seed oil and hulled hemp seed, have been approved to safely be used in food or dietary supplements. None of the intoxicating or synthetic cannabinoids commonly found in consumable hemp products sold in gas stations, vape shops, and online have been approved.
- Despite the responsibility to regulate these products and their violation of the FDCA, the FDA has only taken enforcement actions when products have made egregious drug claims.
- This lack of enforcement means that alongside state regulated cannabis products and safer, natural cannabinoid products derived from hemp like those containing CBD, consumers can find a third category of cannabis products for sale: hemp derived products that are intoxicating and/or produced by chemical synthesis . These products are not compliant with federal or state product safety standards, often have higher levels of THC than are allowed in state licensed cannabis stores, and are created using chemical synthesis without regulatory oversight.

Outline of Recommended Regulatory Structure – Cannabis Market Products

With the federal government not yet stepping in to limit the proliferation of this third category of cannabis products, the burden falls on Vermont and other states to protect the public. We propose regulating consumable hemp products in the following manner:

- All intoxicating hemp products, defined as consumable hemp products with 1 mg or greater of total THC per serving or with more than 10mg of total THC per package, will only be allowed to be sold through the adult-use and medical markets, and will be subject to the same testing and public health regulations as adult-use and medical products, including product registration. Full spectrum tinctures, capsules, and salves with up to 1.5 mg THC per serving and a ratio of THC to CBD of 1:20 or greater will be considered non-intoxicating and will not be limited to the adult-use and medical cannabis market.
- Intoxicating consumable hemp products with 1 mg or greater of any synthetic cannabinoid per serving will only be allowed to be sold through the adult-use and medical markets and will be subject to the same testing and public health regulations as adult-use and medical products, including product registration.
- All manufacturers of intoxicating hemp products described in the first two bullets must be licensed manufacturers under the adult-use or medical program pursuant to Board Rule 1.

Outline of Recommended Regulatory Structure – General Retail Products

- Consumable hemp products that are not limited to the cannabis market because of their level of intoxicating or synthetic cannabinoids may be sold outside of adult-use and medical dispensaries through general retails or online.
- The Board will begin requiring all hemp processors and hemp product manufacturers who are making CBD and other appropriate hemp-derived products to be registered by the Board as a hemp processor by January 1, 2023.
- The Board will ensure that the businesses it registers comply with all the relevant regulations, but additional enforcement actions will need to be taken by additional government agencies and law enforcement to ensure that general retail locations and vape shops only have approved hemp-derived products like CBD products and are not offering prohibited products, like intoxicating Delta-8 products.
- Hemp cultivation will be regulated by the United States Department of Agriculture.

National Overview

- **Federal Status of Hemp**
- **Consumable Hemp Products**
- **The Current Problem**
- **How Other States Are Addressing the Issue**

Federal Status of Hemp – 2018 Farm Bill

The current issue with consumable hemp products originated with the 2018 Farm [Bill](#), which defined hemp as "*the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis*" and removed it from the CSA.

The legislation categorized hemp as an agricultural commodity under the regulatory purview of the USDA in coordination with state departments of agriculture or tribal governments. The USDA published a final [rule](#) 1/19/21, effective 3/22/21, that provides regulations for hemp production and removes hemp-derived products from CSA Schedule 1 status.

But removing hemp from the CSA did not "legalize" all products containing hemp derived ingredients. The 2018 Farm Bill expressly preserved the FDA's authority to regulate products containing hemp ingredients under the FDCA, as well as other product safety levels and regulations

Federal Status of Hemp – FDA Oversight

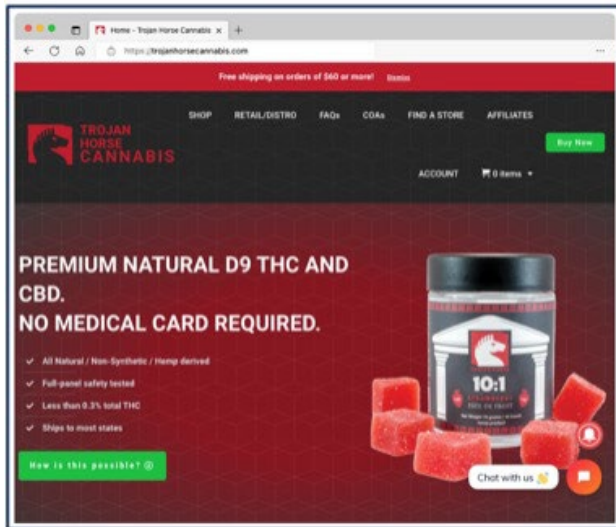
Removing a substance from the list of controlled substances does not make that substance eligible to be automatically put into food, drinks, dietary supplements, and other consumable substances. The 2018 Farm Bill legalized hemp as a crop, but any consumable product still needs to follow the federal product safety rules before it can be legally sold.

The traditional standards for food safety require that the hemp-derived ingredients be "Generally Recognized as Safe" (GRAS) or approved as a New Dietary Ingredient" (NDI). Certain hemp-derived ingredients like hemp seed oil and hulled hemp seed have already been determined to be GRAS for use in human food.

Some naturally-derived cannabinoids like CBD exhibit characteristics of products that would be deemed to be GRAS. However, intoxicating cannabinoids like THC or many of the synthetically derived cannabinoids found in products being sold in non-licensed stores and on the internet have not been approved and do not fit the profile of products that will ever be approved.

Consumable Hemp Products – Overview

But despite existing food safety regulations, the popularity of hemp products has exploded since 2018. In addition to the traditional industrial products made from hemp like rope, consumable hemp products containing various cannabinoids have proliferated.



Some of these products are focused on naturally derived cannabinoids like CBD, which is likely safe and may provide some health benefits. But others focused on intoxicating or synthetically produced cannabinoids are also readily available in stores around the state and for delivery online.

Consumable Hemp Products - Novel and Innovated Cannabinoids

- While THC and, to a lesser extent, CBD, are the most well-known and popular cannabinoids, scientists have identified over 100 cannabinoids contained in small amounts in the cannabis plant, most of which we know little about.
- Natural cannabinoids like Delta-9 THC and CBD have been consumed by humans throughout history.
- With advances in science and manufacturing techniques, novel cannabinoids, those which appear in lower concentrations naturally, now can be extracted from the plant and isolated or manufactured by converting CBD into various minor cannabinoids.
- Delta-8 THC and Delta-10 THC are examples of the commonly manufactured novel cannabinoids that are infused in food and dietary supplements now which have never been consumed in large quantities by humans before.

Consumable Hemp Products – Health and Safety Issues

This proliferation of intoxicating and/or synthetically derived hemp products have created a number of health and safety issues around the country. The three most pressing problems, which Vermont needs to address immediately, are:

1. Intoxicating cannabis products are available outside of the regulated cannabis market where they can be sold to children and where there are no consumer public safety standards;
2. Many of these products are created using unsafe manufacturing processes that can leave harmful or toxic substances in the finished products; and
3. Dangerous and/or intoxicating products are found on shelves next to safer, natural products, like CBD, which can confuse consumers.

The Current Problem – How Did We End Up Here?

- Unfortunately, many companies are taking advantage of the benefits that come from hemp's removal from the CSA but are not complying with their obligations under other aspects of federal law.
- As a result, intoxicating and unsafe products are being sold through the general commercial market, such as shipping products through common carriers like FedEx and UPS and selling them in vape shops and general retail locations like gas stations and convenience stores.
- Thus far, the FDA has taken a very limited approach to enforcement, only initiating enforcement actions against companies that have made egregious health and safety claims.

The Current Problem - Concerns with Novel Cannabinoids

- Some hemp products are marketed as federally legal due to their removal from the CSA despite likely violations of the FDCA and other product safety laws. This include products manufactured through chemical processes that result in unidentified by-products potentially unsafe for consumption. It also includes intoxicating products, both naturally and chemically produced.
- There have been significant public health issues caused by consumable products containing hemp ingredients due to the proliferation of intoxicating and synthetic products. These products have not been evaluated or approved by the FDA for safe use and their lack of regulatory oversight is a cause for concern. While we have better understanding of the effects of commonly used cannabinoids like THC and CBD, there is almost no data on the safety of manufacturing or concentrating cannabinoids that occur naturally in only trace amounts.

The Current Problem – The Size of the Intoxicating Hemp Market

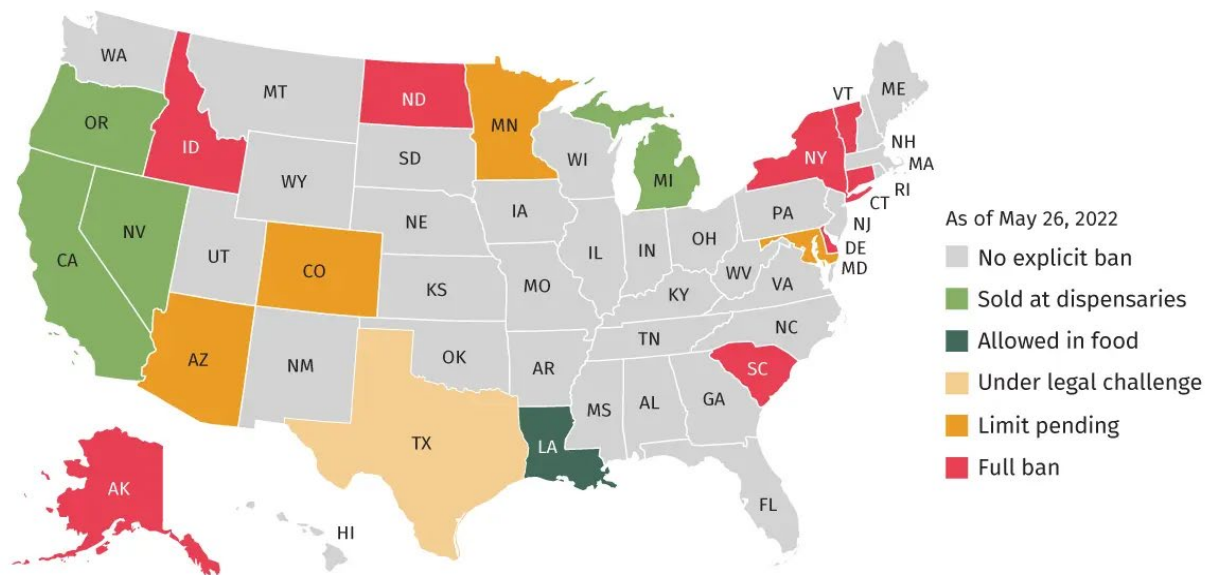
Potentially unsafe consumable hemp-derived products are not a small problem. A recent study in Colorado shows that one of the more popular hemp-derived cannabinoids, Delta-8 THC, is already a \$500 million industry in that state and is expected to grow to more than \$800 million in 2023 with a supply chain extending across the US.

Recent increases in availability and reported incidents involving products with delta-8 have caused both the [FDA](#) and [CDC](#) to release health advisory bulletins addressing the issue. While the advisory bulletins highlight the significance of the issue, states like Vermont need to step up to regulate such products to prevent larger segments of the market from turning to these unregulated products.

How Other States Are Addressing the Issue

States are split on how to address the issues regarding consumable, intoxicating hemp products. The details of each state differs, and some regulate consumable hemp products strictly and do not differentiate between intoxicating and non-intoxicating, but this map is illustrative* of the various approaches and where things stood as of May 2022:

Hemp-derived Intoxicants by State



Source: MJBizDaily research

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*The accuracy of the information in the map has not been verified by the Board

Regulatory Structure

- Goals
- Products Limited to the Cannabis Market
- Products Allowed in the General Retail Market
- Cultivation
- Enforcement

- Remove unsafe products from the market
- Limit intoxicating products to the adult-use and medical markets
- Promote Vermont's local hemp businesses
- Give Vermont consumers access to safe, regulated products

Products Limited to the Cannabis Market

- The CCB does not believe that intoxicating products nor products containing synthetic cannabinoids should be available to Vermont consumers outside of the existing adult-use and medical markets.
- The CCB will clarify that these products would be allowed through the adult-use and medical markets if they meet all other health and safety requirements, including:
 - requiring all product manufacturers and retailers to be licensees;
 - complying with testing requirements;
 - following manufacturing standards;
 - registering all products with the Board;
 - complying with packaging requirements, including those requiring child-resistant packaging and those prohibiting plastic packaging; and
 - subjecting these products to adult-use cannabis taxes.

Defining "intoxicating"

- The Board plans to define intoxicating rather than designating specific cannabinoids as intoxicating because a cannabinoid is only likely to be intoxicating at certain levels.
- The Board initially will deem a product intoxicating if it contains more than 1mg of total THC per serving or more than 10mg per package. One exception to the per serving or per package total THC threshold will be full spectrum tinctures, capsules, and salves with up to 1.5 mg THC per serving and a ratio of THC to CBD of 1:20 or greater. These products will initially be considered non-intoxicating and will not be limited to the adult-use and medical cannabis market. This calculation may need to be adjusted as science and research evolve.
- Any product deemed intoxicating would only be eligible for production and sale through the adult-use or medical markets.

Defining "synthetic"

- The Board plans to define a "synthetic cannabinoid" as "a cannabinoid like compound that was produced using chemical synthesis, chemical modification, or chemical conversion (including in-vitro biosynthesis and bioconversion) of any method or type except for those produced through the decarboxylation of naturally occurring cannabinoids from their acidic form".
- Any product with more than 1mg of a synthetic cannabinoid per serving would only be eligible for production and sale through the adult-use or medical markets, where it would need to meet all the manufacturing requirements and be approved by the Board through the product registration process before becoming available to consumers.

Public health and safety

- While hemp-derived, intoxicating products and products containing more than 1 mg of a synthetic cannabinoid will be eligible for sale through the adult-use and medical markets, they still will need to comply with all existing public health and safety regulations.
- These products will be subject to strict testing requirements, age-gated sales, labeling and packaging regulations, limits on total THC per package, etc. Only after complying with those rules would the products be eligible to be sold to consumers.
- The CCB plans to initially prohibit synthetic cannabinoid products containing Delta-8, Delta-10, or other novel cannabinoids for which insufficient data exists to show that it is safe for human consumption.

Product registration

- Like with other cannabis products, consumable hemp products that are either intoxicating or which contain at least 1mg of a synthetic cannabinoid per serving will be required to be submitted to the Board for product registration.
- The Board will confirm that all such products meet packaging, labeling, testing, and other public health requirements before they will be eligible for sale to the public.
- Such products that are not registered and approved by the Board will not be eligible for legal sale anywhere in Vermont.

Products Allowed in the General Retail Market

- Hemp derived products that are not intoxicating and that do not contain more than 1mg of a synthetic derived cannabinoid would be available for purchase outside of the adult-use and medical markets.
- This means that products containing naturally occurring cannabinoids like CBD will be available at regular retailers and online. It also means that consumers at those retailers should not see safe and unsafe products on the same shelves, reducing confusions and potential harm.
- The Board will begin registering hemp processors intending to produce products for the general retail market in January, 2023.

- Hemp cultivation will remain under USDA's regulatory overview
- The 2018 Farm Bill directed the USDA to federally regulate hemp
- We believe a program managed directly by the USDA in Vermont is sufficient and allows for more focused resources on consumable hemp
- The federal program does not allow much flexibility while requiring states to shoulder the administrative costs
- Shifting the oversight to USDA decreases this burden and allows Vermont to focus on programmatic areas where it has regulatory discretion, e.g. areas not under USDA control, such as processing and retail sales of finished products

- Products sold through the cannabis market → The CCB will enforce the rules
- Non-intoxicating hemp products manufactured for the general retail market → The CCB plans to require registration for hemp processors in January, 2023
- Non-intoxicating products sold through the general retail market, including online sales → The CCB will not have a role in enforcing the rules against products being sold. Responsibility for enforcement will fall to law enforcement and other government agencies.

If the legislature would like the CCB to have an additional role in enforcing rules against non-intoxicating hemp derived products sold through non-licensed stores, additional funding and staffing would be required.

Fee and Budget Recommendations

- New License Fees
- CCB Projected Staffing Requirements
- CCB Projected Appropriations Requirements

License & Registration Fees

Business type	Application Fee	Registration Fee
Hemp Processor (producing products with <1 mg THC per serving)	\$25	\$1,000

Business type	Application Fee*	License Fee*
Hemp Manufacturer (producing products with \geq 1 mg THC per serving)	\$1,000	\$750 - \$15,000, depending on manufacturing tier

*these are existing fees set in statute for cannabis product manufacturers

CCB Projected Staffing and Appropriations Requirements

The recommendations for hemp regulation set forth in this report would not require additional compliance or licensing staff at this time.

However, to protect consumers and ensure the quality of Vermont cannabis and hemp-derived products, and in accordance with Act 158 Sec. 4, the CCB proposes instituting a quality assurance program.

- This program would conduct compliance, quality control, and R & D testing to assist Vermont hemp and cannabis businesses build their reputations and ensure the CCB maintains the integrity of the programs it administers.
- The CCB requests an appropriation sufficient to cover 2 chemists, a lab director, and \$850,000 for lab equipment.

If the legislature directs the CCB to develop and enforce rules governing non-intoxicating hemp products, the CCB would request additional staffing to accommodate that workload.

Other Recommendations

- Endorsement Program for Made in Vermont Products
- Public Education Campaign
- Prioritize Enforcement to Remove Unsafe Products from the Market
- Clarify the Tax on e-Cigarettes to Exclude Cannabis Products
- Advocate for More Research

Recommendation: Expand existing "Vermont hemp product and Hemp-infused product" program so consumers can ensure they are purchasing local products.

- This program will protect public health and safety and boost local economies
 - The state will promote the endorsement, thereby increasing visibility for local Vermont businesses and generating demand for compliant, local products
 - Providing regulatory certainty and promotion of local businesses will incentivize new businesses to invest in Vermont
 - An endorsement program would allow Vermont consumers to have the peace of mind that their consumables have been grown and developed under the regulatory purview of the State of Vermont
 - Consumers who want to prioritize supporting local business will know which products are made by their fellow Vermonters.
- A simple registration process that results in a state-approved endorsement that allows consumers to make more educated decisions when purchasing products
 - These endorsements can be displayed on product packaging and labeling as well as around retail locations through a badge or medal
- Vermont has a strong opportunity in hemp and this program would bolster our local hemp growers, even as the hemp market gets more competitive

Endorsement Program for Made in Vermont Products - Maple as the Model

The Maple Program implements the Vermont Maple Law and Regulations that establish quality standards and food safety labeling requirements for pure maple syrup and other maple products. A similar program could be built out for hemp.

- Program staff conduct periodic inspections of maple products sold at retail locations, respond to consumer complaints, and provide technical assistance to producers and packers regarding regulatory requirements.
- The law, Title 6 Chapter 32, trademarks certain terms, sets advertising guidelines and labeling standards, and establishes other areas of the program.
- The Program serves 3 main functions:
 - Allows the state to have a level of control over the quality of products it gives its approval to
 - Assures consumers the product they are purchasing meets a minimum standard
 - Promotes local Vermont business and give consumers an identifiable symbol that signifies the product is from Vermont

Endorsement Program for Made in Vermont Products – Similar Programs in Other States

- Colorado: ["By Colorado"](#) program to promote state companies and state reputation
 - Companies proud that their products are made, designed or grown in Colorado can apply to use a state-designed logo
- New York: ["New York State Grown and Certified"](#) program to make it easy for consumers to identify local, safely-handled, and environmentally responsible agricultural products.
 - Voluntary program to be able to label products with a seal that indicates that the farms the products come from have been inspected for safe food handling and environmental stewardship
- Wisconsin: ["Something Special from Wisconsin"](#) program administered by the WI Department of Agriculture to help members stand out on grocery store shelves and connect consumers with genuine Wisconsin products
 - Program members must certify that at least 50% of a products ingredients, production, or processing is from or completed in-state to be able to use A red and yellow program logo provides a quick way for consumers to identify products

Recommendation: Create a public awareness and educational campaign designed to encourage the purchase of products vetted by the CCB.

- Because there is difficulty regulating out-of-state, unregulated consumable hemp products, there needs to be significant investment in educating consumers and steering them towards safer products and those under the CCB's jurisdiction.
- The state should develop outreach and educational programs designed to inform consumers about the differences between unregulated, intoxicating and/or synthetically derived hemp products and safer products like CBD.
- Any outreach or program should aim to inform Vermont consumers of both the dangers of consuming products not regulated by the CCB as well as the benefits of purchasing products regulated by the state.

Recommendation: Work with other agencies and properly fund enforcement actions to find and remove non-compliant products from the market.

- Currently, many hemp companies are making intoxicating and/or unregulated products and selling them online or in Vermont stores in violation of federal and state law.
- The Board can control what is sold through licensed cannabis stores but will not be in a position to enforce the rules against websites, convenience stores, or other unlicensed outlets that may be selling unregulated hemp products.
- The Legislature should ensure the proper inspectors and enforcement officials are in place to find and remove such products from shelves.

Recommendation: Clarify the tax on e-cigarettes so that cannabis products are not included.

- Cannabis and tobacco are two different products, and the taxation on them should reflect the different challenges the state faces in regulating each product.
- The Legislature should clarify that cannabis products, including vaporizer cartridges, are not subject to the State's 92% tax rate on electronic cigarettes.
- Cannabis faces competition from a very robust, untaxed illicit market.
 - Such high taxes will push consumers toward out-of-state or illicit products that the CCB is trying to steer buyers away from.
 - As noted in other legislative reports submitted by the CCB, unregulated cannabis products may contain residual solvents, additives, or diluents that are harmful for human consumption.

Recommendation: Vermont should encourage our federal partners to allow for additional research, particularly on intoxicating and synthetically-derived cannabinoids.

- Changes must be made to current federal standard for research by allowing study of the actual products available commercially throughout the country.
- It is universally agreed upon that there is a great need for further research on cannabis and its cannabinoids.
- More research and scientific data allows for smarter and safer policy decisions.
- To most benefit cannabinoid research, there needs to be financial investment as well as a regulatory framework.
 - Laws currently in place restrict the ability of necessary research.
 - The effectiveness of research funding is maximized when paired with a regulatory framework that is favorable to research and allows for safe scientific advancement.