

Product Text Labels Indicate the Presence of Other Pharmacologically Active Ingredients in many OTC hemp- and CBD-containing Preparations



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Introduction

The 2018 Farm Bill allowed for the expansion of the sale of Cannabidiol (CBD) products by changing the legal status of cannabis plants that meet the definition of industrial hemp. With the addition of this bill, any hemp based or CBD products that are found to have less than or equal to 0.3% THC are allowed to be sold in common commercial spaces, such as grocery stores and pharmacies. With an emphasis on industrial hemp as the source of naturally-occurring cannabinoid compounds, a niche market for cannabidiol (CBD)-containing products was quickly established, which quickly saw a rapid and unprecedented growth of many combination products.

Although the U.S. Food and Drug Administration (FDA) has retained oversight of all cannabis-based products, labelling of hemp-derived products for retail markets remains largely unregulated. Under federal law, CBD cannot be added to foods, beverages, sold as a dietary supplement or marketed for a therapeutic benefit, however the perceived health benefits of CBD as an acceptable and safe ingredient contribute to the growing market for this health product.

Objectives

The objective of this study is to evaluate the range of over-the-counter (OTC) hemp- and CBD-based products available to consumers and determine the prevalence of other pharmacologically active agents identified as ingredients in these products.

Products were scored based on:

- Manufacturer
- Formulation
- Active Ingredients that contributed to activity of the product
- Inactive Ingredients
- Amount of CBD in each product
- Percentage of CBD in each product
- Presence of full-spectrum hemp
- Presence of full-spectrum CBD
- Presence of CBD isolate
- Presence of vitamins
- GMP Certification

	Average number of Active Ingredients (#)	Average number of Inactive Ingredients (#)	Average Amount of CBD (mg)	Average % of CBD in product (%)	% of products containing Menthol (%)	% of products containing Vitamins (%)
All products (N=33)	3.76	7.21	402.46	1.124	39	30
Topical (N=25)	4.28	7.56	324.08	0.85	39	36
Oral (N=6)	1.67	6.5	815.67	2.62	0	17
Bath (N=2)	3.5	5	142.5	0.05	0	0

Methods

During the months of May 2020 until February 2021, two large pharmacy chains and one medium-sized grocery store located in the Pacific Northwest were surveyed. All products that were located in the store and were clearly labelled as containing Hemp or CBD were included in the study, while all other supplements were excluded. Products that were locked behind a display cabinet or located in the actual pharmacy were excluded as well. Any products that did not accurately report the amount of CBD in the product were excluded. Products that did not list the total weight of the product were excluded from the analysis.

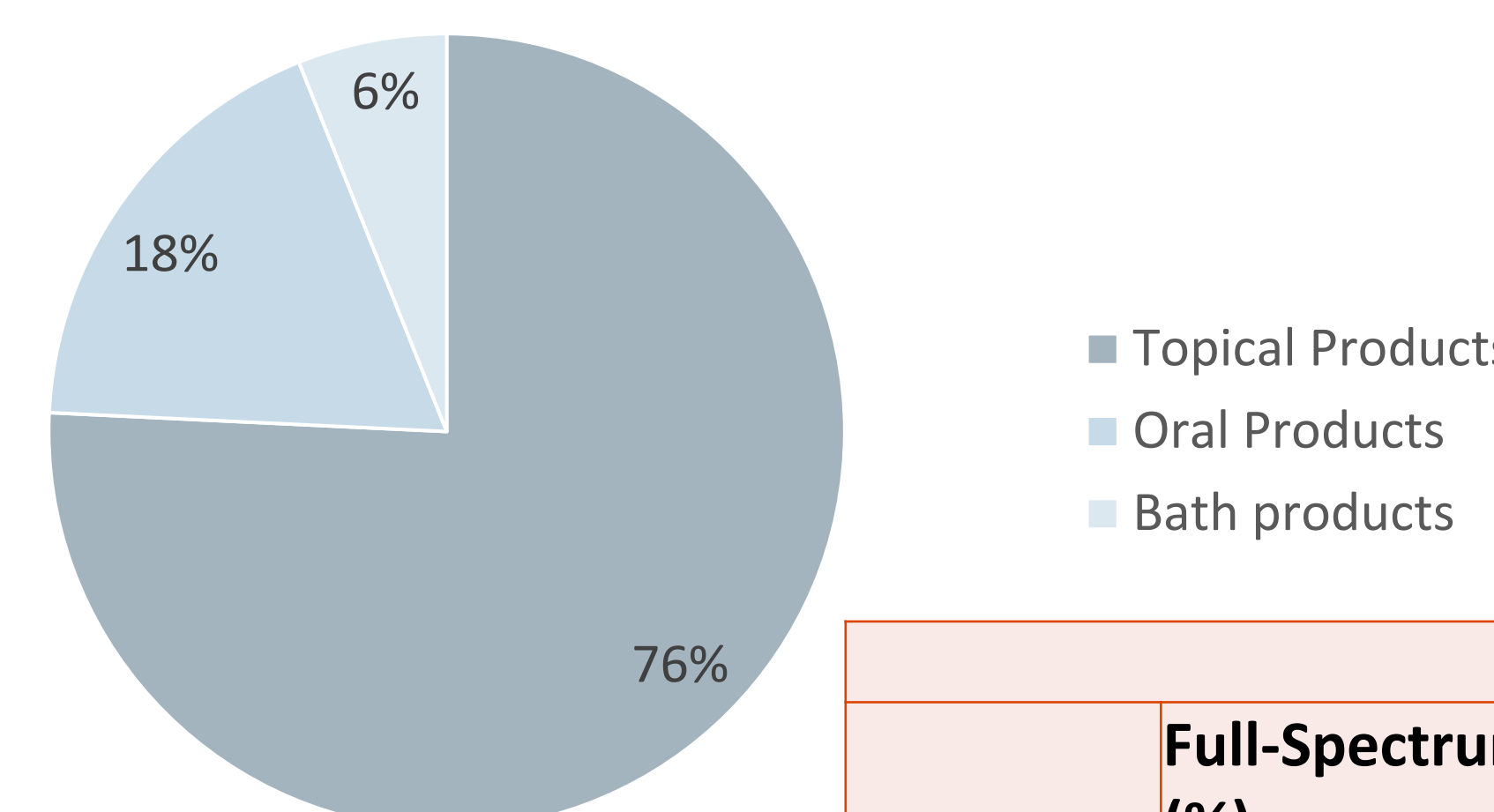
Products were organized based off of manufacturer as well as product lines and formulations. Ingredients of each of the the products were organized based off of inactive or active ingredients that could be used to contribute to the overall activity or perception of activity of the base product. Identification of pharmacologically active ingredients on the product label was validated using the National Medicines Comprehensive Database. Amount of CBD in the product was recorded as well as the percentage of CBD that made up the entirety of the product. Products were also graded on the labelling of type of CBD product located in the base product: full spectrum hemp, full spectrum CBD or CBD isolate. Products were also categorized based off of the presence of labelling indicating whether the products were found to be THC-Free or THC-Compliant. The presence of vitamins was also included in the data analysis. Good Manufacturing Practice (GMP) certification for each product was also noted.

Results

In total, 33 unique products from a total of 19 different manufacturers were included in the study. Of these products, 25 (76%) were classified to be topical products. Topical products in this study encompassed the following formulations: spray, oil, cream, ointment, lip balm, roll-on, spray, and patches. 6 products were classified to be oral products and 2 products were classified for bathing use solely. (Figure 1). On average for each product, it was found that there were 7.21 inactive ingredients (Range: 1-18) and 3.76 active ingredients that contributed to the activity of the product besides CBD (Range: 1-9 ingredients). When analyzing the active ingredients of the products, it was found that 13 of these products had menthol listed as an active ingredient (39%) in concentrations similar to that of other OTC medicinal products (10% or more). Other frequently found active ingredients included camphor, another topical anesthetic.

Tables 1 and 2 list the findings from the survey of products split into label specific findings and ingredient-based findings.

Figure 1: Distribution of Formulation of Products



Conclusion

This study had found that majority of representative products found in grocery stores and pharmacy chains were topical products with more than one active ingredient that contributed to the activity of the product. A common theme, that was noted amongst topical products especially, was the inclusion of menthol as an ingredient into the product. Menthol by itself acts as a topical anesthetic which can contribute to the "soothing and healing properties" that people often sought out in CBD products, especially, when menthol is given in concentrations that are similar to what is seen in other OTC topical analgesia products such as Icy Hot.® This may cause confusion for patients as they attempt to navigate whether the CBD is affecting them negatively or positively.

Surveying of the products also found that there were inconsistencies amongst CBD products when it came to product labelling. Nearly 45% of the products that were surveyed did not mention if they were THC compliant or if their products were THC free, while 55% of products had some mention of the amount of THC reported to be found in the product. GMP certification was also not evident in many of the products as only 15% of all products had indicated that they were made with Good Manufacturing Practices in mind. This inconsistency in labelling and product manufacturing can lead to safety concerns as well as misdirection by patients who may be looking to use these products to treat their ailments.

Moving forward, more work is needed to determine the prevalence of inconsistencies of labelling of products as well as any safety concerns that may be associated with OTC CBD products.

	Full-Spectrum (%)	Hemp Extract (%)	THC-Free (%)	THC-Compliant (%)	Unknown THC status (%)	GMP-Certified (%)
All products (N=33)	39	61	42	12	45	15
Topical (N=25)	40	60	44	8	48	16
Oral (N=6)	33	67	50	0	50	0
Bath (N=2)	50	50	9	100	0	50

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