

CBD: *The New Hot and Totally Unregulated Supplement*

Introduction

Gaining popularity with the consumer pursuing alternative remedies, the rise of CBD supplements has skyrocketed in the past few years. CBD can be used in every product imaginable. However, some consumers may still be asking: “What is CBD? And why should it matter to me?” CBD is an abbreviation for Cannabidiol¹. This component is extracted from the Cannabis sativa plant. Marijuana can also come from the Cannabis sativa plant (as well as the Cannabis indica plant). Different strains of these plants will yield either high quantities of CBD or THC. The difference between CBD and THC is that CBD by itself is not a hallucinogenic and does not cause the consumer to develop a high. Consumers reach for CBD for a variety of numerous health reasons such as pain relief, lowering anxiety, as a sleep aid, and treating some underlying chronic illnesses¹. Though many benefits still have to be researched, discovered, and validated, the use of CBD oils and products have a strong following.

How are CBD Products Made?

The process of extracting CBD from the hemp plant is complicated. There are three main ways to extract CBD from the harvested hemp buds. The first, and most widely used process in the industry, is through CO₂ extraction. This process uses carbon dioxide in a liquid form as a solvent to separate the CBD component from the numerous chemicals present in the plant tissue². An older process, used to make a more concentrated end product, is extracted with the use of ethanol. Each bud is soaked in ethanol, distressed, and then the entire process is heated to extract the various components within the hemp². The last

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option is through the use of hydrocarbon extraction. Other solvents such as butane, hexane, propane, etc., can be used to extract the CBD component from the plant. However, with the use of these solvents, the process can be increasingly dangerous due to their flammable nature². Each process has advantages and disadvantages with respect to the product produced, safety, and ease of the process. Once the oil or waxy substance has been removed, it needs to be purified such that only the CBD isolates remain. Without the purification step, there is still a trace amount of THC in the product as well as other cannabinoids. The pure product only containing CBD is then transformed into consumable packaged goods that consumers desire, such as oils, gummies, capsules, topicals, etc³.

Is it Legal?

In 2018, Congress passed the Agriculture Improvement Act of 2018 (“Farm Bill”), which was then signed into law at the end of the year.

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In 2019, it went into effect, legalizing the hemp plant on a federal level when it contained less than 0.3% THC. The Farm Bill removed hemp from the Controlled Substances Act and allowed for expanded hemp commercial cultivation. However, it's not that simple. The 0.3% THC tolerance applies only to dried raw hemp plants. The highly refined CBD products on store shelves are a far cry from dried raw hemp plants. Additionally, there is a compliance patchwork of state-level compliance. Only 48 out of 50 states have legalized the use of CBD, and the legal conditions differ between states as well. In Idaho, CBD products must be tested and contain 0% THC⁴. If these conditions are not met, the product is considered illegal. Nebraska law only allows a limited number of licenses to be awarded during the year to grow, process, and manufacture hemp and CBD products⁵. However, given that no CBD products are approved by the FDA except one, Epidiolex (used to treat two rare forms of epilepsy), how can CBD products be made into food and health supplement products? According to the FDA, “It is currently

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illegal to market CBD by adding it to a food⁶. The lack of regulatory enforcement and oversight has resulted in the CBD industry being consistently referred to as the “Wild West.” The absence of regulation can and has resulted in inconsistent product quality, purity, and exposing unsuspecting consumers to unintentional ingestion of THC, potentially resulting in failed drug tests. Sounds risky, doesn't it?

Is it Safe?

Everyone seems to be using CBD in some form these days. From your grandma to your fitness trainer, in the format of gummies to topicals. However, is this product even safe to use? According to the FDA,

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“CBD has the potential to harm you, and harm can happen even before you become aware of it.”⁶ Initial studies have shown potential links to liver damage and reproductive toxicity.⁶ CBD research and studies still have much work to do, and many questions to be answered. What are the effects on the body after taking CBD for an extended period of time? Are newborns or small children impacted differently by CBD? Can it harm the development of a fetus? Most of the research on these topics is still in the early stages, and many of the answers have yet to be discovered.

However, it's important not to underestimate the potential for CBD.

So, Why the Craze?

CBD products have swiftly become the new “it” thing in the medical world. The market has erupted and is poised to continue to grow. According to Data Bridge Market Research, the market for CBD is expected to rise by 31.9% in the next seven years⁷. But why?

Currently, consumers view CBD as a cure-all. Severe anxiety? Check. Sleep deprivation? Check. Chronic pain? Check. Epilepsy? Check. It has been leveraged as an alternate resource by those who have run out of options and use it to regain their quality of life⁸. However, with the product being sold at premium prices and promising so many benefits, a consumer would have to believe that the companies would be accurate about their contents, right? Wrong.

The Scope of Testing

Clean Label Project's CBD Study Methodology

In order to ensure the quality and authenticity of the top CBD products available to consumers, Clean Label Project purchased and tested 208 of the top products for quality, content, heavy metals, and plasticizers. This study used analytical chemistry in an accredited laboratory to test each sample. Clean Label Project simulated the consumer shopping experience by purchasing products from grocery store shelves, brand websites, or from Amazon.com. This allows the findings to be more consistent as to the true contents of products sitting in medicine cabinets, gym bags, or kitchen pantries right now. Prior to the CLP study, the FDA also exhibited concerns regarding the purity and potency of CBD products on the market⁹. Much more research is needed in this field.

The Results

The results of the study illuminated new concerns over the authenticity of the products and the accuracy of the labels.

Key Finding #1: THC-Free is Not Always the Case

According to the Clean Label Project study, 45% of the CBD products tested had detectable levels of THC¹⁰. The 2018 Farm Bill removed Hemp as a federally controlled substance as long as it contained no more than 0.3% THC by weight in dry hemp¹¹. As mentioned before, the highly processed and refined oils and topicals are a far cry from dry agricultural hemp. Therefore, Clean Label Project questions if this application of the Farm Bill should even apply to processed hemp

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(CBD). Additionally, how can a product claim to be THC-free if it still has detectable levels of THC? Maintaining the legal limit for THC contents does not qualify a product as being THC-Free. False claims such as these can be very dangerous to consumers. THC is a Schedule I substance controlled by the federal government¹². If THC levels can be detected through CLP's testing, they can also be detectable on a human drug screening. This means that someone taking CBD for chronic pain could fail a drug test due to the burgeoning CBD industry's inconsistent testing methods and labeling. Even though a consumer may not have intentionally used a THC product, the levels of THC in the CBD products that they have used could have the unintentional result of a positive drug test reading.

It's also important to note that in some cases, Clean Label Project THC test results yielded THC levels that exceed maximum THC thresholds allowed in recreational marijuana products.

Key Finding #2: You Can't Always Trust What It Says on A Label

The amount of CBD concentrate in a product should be accurately reflected on the label. However, this is not always the case. In the

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products tested, Clean Label Project identified a wide range of inconsistent potency labeling from no CBD detected whatsoever to containing 700% the amount listed on the label¹⁰. This inconsistency makes it hard for the consumer to decide which concentration is right for them. Using a product that contains no CBD, and therefore has no effect, can discourage a consumer when they have paid premium prices for that product. On the other side of the spectrum, a product containing 700% of what the label declared can pose some health risks, including fever, headaches, nausea, etc¹³.

It is uncertain whether the absence of CBD in some finished products was intentional economic adulteration purported on consumers or poor quality assurance and quality control in this emerging industry. In either case, in some products, consumers are not getting what they pay for.

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Key Finding #3: Elevated Lead Levels

Lead is an element that is naturally occurring and found within the earth's crust, and it can also be introduced to food and consumer products through human causes, including mining, fracking, and industrial agriculture¹⁴. Though it does have uses, it is toxic to humans and can pose serious health risks such as lead poisoning, infertility, and cardiovascular disorders¹⁵. The average lead content in the CBD products tested was 34 ppb (parts per billion), making it the highest of any consumer product Clean Label Project has tested to date¹⁰. Hemp plants are known for bioaccumulation of heavy metals¹⁶. This means that hemp plants are used to remove heavy metals (such as lead) from the soil¹⁷. Only through a strict ingredient sourcing program and

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robust testing can a reputable CBD brand proactively minimize consumer exposure to this known contaminant.

Key Finding #4: Phthalates

Phthalates are used in plasticizers as an agent to make them flexible and increase strength¹⁸. They are found in everyday items such as tubing, packaging, films, and containers¹⁸. Though no short-term effects are found to be caused by phthalates, long term exposure can lead to chronic health risks. Studies have linked long-term exposure to phthalates to endocrine disruption and the development of cancer¹⁹. While doing the same tests for different product categories, Clean Label Project typically finds the phthalate count to be in double-digit ppb¹⁰. CBD products, on average, contained over 1,000 ppb¹⁰. Without knowing for certain, Clean Label Project hypothesizes that non-food grade tubing is being used in the extraction method and is contributing to these elevated levels of phthalates.

What Should a Concerned Consumer Do?

1. **If you have questions, ASK!** If you are concerned about the safety or quality of the CBD product you are using or considering, visit the company website to learn about what testing methods they use, what they test for, safety protocols on the products and the quality of their products.

2. **If it looks too good to be true, it probably is.** Some brands use Certificates of Analysis to prove they've performed testing. Some brands use poor levels of detection and quantification for testing to give consumers a false sense of security about the product

quality and purity. These Certificates of Analysis will say ND (Non-Detect) for a litany of contaminants. In many cases, these test reports are not worth the piece of paper that they are printed on. Because of societal choices around mining, fracking, and industrial agriculture, contaminants occur and are present in products. It's a matter of minimizing consumer exposure.

3. Clean Label Project is another great source of information. Other great reputable consumer websites include ProjectCBD.com and Wholistic Research and Education Foundation.

4. Talk to your doctor. Also, one should always contact their physician prior to adding CBD products to their daily regimen.

What Should a Concerned Brand Do?

1. Trust but verify. Brands that currently produce CBD products should always conduct tests to ensure the safety of the products they are putting on the market. These tests should include ensuring CBD levels are accurate as well as free of THC, heavy metals, plasticizers, and any other chemicals which have proven to cause health concerns to humans or animals.

2. Be mindful of the evolving regulatory landscape. As government regulations are always changing, stay up-to-date on all new regulations and what they mean for your products. As new research is developing, CBD is becoming more widely legalized but it is not yet legalized for food products or dietary supplements⁶. In the future, this might change and open up the market for more opportunities as CBD is better understood.

3. Consider working with Clean Label Project. Clean Label Project offers an evidence-based benchmarked certification program to evaluate product quality and purity. This process includes third-party finished product ISO accredited analytical chemistry testing for over 300 contaminants and product traits.

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