

# Charlotte's Web (Cannabis)

Subjects: Others

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Charlotte's Web is a high-cannabidiol (CBD), low-tetrahydrocannabinol (THC) Cannabis strain marketed as a dietary supplement under federal law of the United States. It is produced by the Stanley brothers in Colorado. It does not induce the psychoactive "high" typically associated with recreational marijuana strains that are high in THC. In September 2014, the Stanleys announced that they would ensure that the product consistently contained less than 0.3% THC. Charlotte's Web is named after Charlotte Figi, born (2006-10-18) October 18, 2006 (age 16), whose story has led to her being described as "the girl who is changing medical marijuana laws across America." Her parents and physicians say she experienced a reduction of her epileptic seizures brought on by Dravet syndrome after her first dose of medical marijuana at five years of age. Her usage of Charlotte's Web was first featured in the 2013 CNN documentary "Weed". Media coverage increased demand for Charlotte's Web and similar products high in CBD, which has been used to treat epilepsy in toddlers and children. It was originally called "Hippie's Disappointment" as it was a strain that had high CBD and could not induce a "high". While anecdotal reports have sparked interest in treatment with cannabinoids, there is not enough evidence to draw conclusions with certainty about their safety or efficacy. Physicians worry that some parents are willing to try treatments before proper research has been conducted, and that they may be disappointed. They are "alarmed by parallels to past miracle-cure manias later proved false..." and "...wary of the heightened placebo effect in treatments involving children, when reports of progress depend on the view of parents."

Keywords: medical marijuana ; low-tetrahydrocannabinol ; placebo effect

## 1. Medical Uses

### 1.1. Evidence

In 2014, there was little evidence about the safety or efficacy of cannabinoids in the treatment of epilepsy.<sup>[1][2]</sup> A 2014 Cochrane review did not find enough evidence to draw conclusions about its use.<sup>[3]</sup> A 2014 review by the American Academy of Neurology similarly concluded that "data are insufficient to support or refute the efficacy of cannabinoids for reducing seizure frequency."<sup>[4]</sup>

The Cochrane review suggests cannabinoids be reserved for people with symptoms that are not controllable by other means, who have been evaluated by EEG-video monitoring to confirm diagnosis, and are not eligible for better established treatments such as surgery and neurostimulation.<sup>[5]</sup> A second review described four placebo-controlled trials of cannabidiol including 48 people with a disease that was not manageable by other means. Three out of four trials reported some reduction in seizures, but no comparison with placebo was possible due to the small number of people in the trials. The drugs were well tolerated.<sup>[6]</sup> A third review found that no reliable conclusions about the effect of cannabis on epilepsy could be drawn due to the poor quality of available data, but further research may be warranted because of the good safety profile observed in small clinical trials.<sup>[7]</sup>

A 2017 study in children with drug-resistant Dravet syndrome, using a comparatively high dose of 20 mg/kg, found cannabidiol reduced convulsive seizures (but not non-convulsive seizures), and resulted in more side effects compared with placebo.<sup>[8]</sup>

Three phase 3 clinical trials completed in 2017 demonstrated the efficacy of cannabidiol in reducing convulsive seizure activity at doses of 10–20 mg/kg per day in children with treatment-resistant Dravet Syndrome and treatment-resistant Lennox-Gastaut Syndrome.<sup>[9]</sup>

### 1.2. Statements

Due to the anecdotal nature of the health claims being made medical bodies have published statements of concern.

A position statement by the American Epilepsy Society states:

The recent anecdotal reports of positive effects of the marijuana derivative cannabidiol for some individuals with treatment-resistant epilepsy give reason for hope. However, we must remember that these are only anecdotal reports, and robust scientific evidence for the use of marijuana is lacking... at present, the epilepsy community does not know if marijuana is a safe and effective treatment, nor do they know the long-term effects that marijuana will have on learning, memory and behavior, especially in infants and young children.<sup>[10]</sup>

## 2. History



Cannabis oil. <https://handwiki.org/wiki/index.php?curid=1252115>

Charlotte's Web was developed in 2011 by the Stanley brothers (Joel, Jesse, Jon, Jordan, Jared and Josh<sup>[12]</sup>) through crossbreeding a strain of marijuana with industrial hemp.<sup>[13]</sup> This process created a variety with less tetrahydrocannabinol (THC) and more cannabidiol (CBD) than typical varieties of marijuana.<sup>[14]</sup> The variety shows potential for medical usage, especially for those who do not wish to experience the typical high of recreational marijuana use.<sup>[15]</sup> As it is so low in THC, the variety was originally called "Hippie's Disappointment",<sup>[16]</sup> and also has been labeled "boring".<sup>[17]</sup> It is a less profitable plant<sup>[18]</sup> with "close to no value to traditional marijuana consumers."<sup>[19]</sup>

The Stanley brothers grow the plants at their farm and greenhouses. A CBD rich oil is extracted from the harvested plants and concentrated through rotary evaporation.<sup>[20]</sup> To make it easier to perform clinical trials, they are planning to move the Charlotte's Web part of their operation to Uruguay. By doing so, they will also be able to import it into any U.S. state as hemp.<sup>[21][22]</sup>

The Realm of Caring Foundation (RoC),<sup>[23]</sup> a 501(c)(3) nonprofit organization,<sup>[24]</sup> was set up by the Stanley brothers to help patients "who can't afford the treatment."<sup>[16]</sup> They have also started "Stanley Brothers Social Enterprises, Inc.",<sup>[22][25]</sup> [26] which has registered the trademark "Charlotte's Web Hemp Products".<sup>[27]</sup> Some products are marketed through CW Hemp (formerly CW Botanicals).<sup>[28]</sup>

## 3. Society and Culture

### 3.1. Legal Status

With the main ingredient being classified as "industrial hemp", (Farm Bill) Charlotte's Web Oil and other CBD products are legal in all 50 states (as long as the THC content is <0.3%) as they are dietary supplements.

The publicity associated with Charlotte's Web has inspired a number of legislative bills, some of which are in the planning stages, and others which have been proposed or actually passed. Children, as "uniquely powerful advocates for medicinal pot across the country,"<sup>[29]</sup> have inspired "the movement to legalize medicinal marijuana," a movement which "has a face like Charlotte's—and it's a young one that's hard to ignore. Lawmakers across the country are pushing legislation to legalize marijuana oil as a treatment for children with epilepsy."<sup>[30]</sup>

Colorado law permits the use of medical cannabis for eight conditions: cancer, glaucoma, HIV/AIDS, muscle spasms, seizures, severe pain, severe nausea and dramatic weight loss, and muscle atrophy.<sup>[44]</sup> The publicity surrounding anecdotal reports of successful treatment of intractable epilepsy with cannabinoids is likely to lead to a surge in interest.<sup>[41]</sup>

In 2013, the parents of a two-year-old with Dravet syndrome confronted New Jersey governor Chris Christie, who signed a bill allowing access for sick children to medical marijuana<sup>[49]</sup> in a controversy dubbed "pot for tots".<sup>[19][31][32]</sup>

In 2014, legislative proposals in Utah,<sup>[33][34]</sup> Arizona,<sup>[35]</sup> New York,<sup>[36]</sup> Washington state,<sup>[19]</sup> Minnesota,<sup>[37]</sup> and Florida<sup>[38]</sup> were considered, where "even some staunch opponents of medical marijuana now are willing to make an exception" to allow the marijuana extract for medical treatment.<sup>[40]</sup>

In Utah, Rep. Gage Froerer, R-Huntsville, said in October 2013: "Nothing in federal or state law prohibits the sale or use of hemp products."<sup>[20]</sup> He pledged to consult with the Utah Substance Abuse Authority, saying: "We need to take a strong look at this and make sure that we as a legislature and we as citizens understand really what this is and what it's not."<sup>[41]</sup> In November 2013, he said he would address "three components in sponsoring legislation: access, quality control and research. He said the Utah Department of Health would probably be involved in quality-control efforts..."<sup>[42]</sup> Annette Maughan, President of the Epilepsy Association of Utah, said: "The current Utah law doesn't exclude its use but also doesn't allow for its use. We are in limbo until Utah lawmakers decide what to call it."<sup>[41]</sup> On March 21, 2014, Gary Herbert, the governor of Utah, signed a bill giving "families access to the marijuana extract for treating epilepsy."<sup>[35]</sup> The state bill, HB0105, allows import of Charlotte's Web extract across state lines from Colorado to Utah, and covers only use for intractable epilepsy with the consent of a neurologist.<sup>[33][34]</sup> Also on March 21, 2014, an Arizona court found "that Arizona's medical marijuana law allows consumption of the plant in extract form."<sup>[35]</sup>

On March 20, 2014, the Florida House of Representatives Budget Committee passed the "so-called Charlotte's Web measure (CS/HB 843)"<sup>[39]</sup> designed to limit prosecutors' ability to prosecute those in possession of low THC/high CBD marijuana ("0.5 percent or less of tetrahydrocannabinol and more than 15 percent of cannabidiol") used for treating seizures. The law took effect July 1, 2014.<sup>[43][44]</sup> Since then, Florida legislators have passed a bill with bipartisan support legalizing the use of Charlotte's Web,<sup>[45]</sup> and Governor Rick Scott signed the "Compassionate Medical Cannabis Act of 2014" (SB 1030)<sup>[38][46]</sup> into law on June 6, 2014. The law is also referred to as the "Charlotte's Web" law.<sup>[47][48]</sup> The law specifies the number of distribution centers, which types of nurseries can grow the plants, requires various other controls,<sup>[49]</sup> and provides funding for research.<sup>[38]</sup>

- Federal legislation was introduced in 2014 (U.S. 113th Congress 2013-2014) but was never brought to a vote and died in committee.<sup>[50][51][52][53]</sup>
- Rep. Perry, Scott (R-PA-4) introduced to the U.S. 114th Congress (2015-2016) H.R.1635 - Charlotte's Web Medical Access Act of 2015<sup>[54]</sup> with 62 bipartisan co-sponsors.<sup>[55]</sup> It has not been voted on yet, but it has made progress and been referred to the House Committee on Energy and Commerce, the House Committee on the Judiciary, the Subcommittee on Health and the United States House Judiciary Subcommittee on Crime, Terrorism, Homeland Security and Investigations.
- The Therapeutic Hemp Medical Access Act of 2015 (Senate 1333) was introduced (not passed yet) with 11 co-sponsors to amend the Controlled Substances Act to exclude cannabidiol and cannabidiol-rich plants from the definition of marijuana. It was referred to the Committee on the Judiciary.<sup>[56]</sup>

On October 31, 2017, the FDA sent warning letters to four CBD marketers, including Stanley Brothers Social Enterprises, LLC (d/b/a CW Hemp), the producer of Charlotte's Web. They were warned "against making medical claims about cannabidiol (CBD). The agency also took issue with the businesses marketing CBD products as dietary supplements".<sup>[57]</sup>

### 3.2. Reactions to CBD-Only Laws

The federal Schedule 1 drug classification<sup>[58]</sup> blocks broad scientific research on cannabis. However, in late 2015, the United States Drug Enforcement Administration (DEA) eased some regulatory requirements imposed by the Controlled Substances Act (CSA) for those who are conducting FDA-approved clinical trials on cannabidiol (CBD). These modifications will streamline the research process regarding CBD's possible medicinal value and help foster ongoing scientific studies.<sup>[59]</sup>

But the Marijuana Policy Project has expressed frustration over the fact that many legislative efforts inspired by Charlotte's Web are aimed at only legalizing low or no THC, high CBD medical marijuana products. They believe that such legislation is too restrictive and ignores claimed benefits of THC, leaving "behind around 98% of the individuals who can benefit from it."<sup>[60]</sup> Referring to the "Charlotte's Web Medical Hemp Act of 2014", an editorial in *Ladybud Magazine* expressed concern that the law "leaves thousands of patients out in the cold without safe, legal access to medical cannabis. It also ignores science that seems to indicate that whole plant medicine is optimal."<sup>[61]</sup>

### 3.3. Etymology

Charlotte's Web is named after an American girl, Charlotte Figi. She developed Dravet syndrome (also known as severe myoclonic epilepsy of infancy or SMEI) as a baby. By age three, Figi was severely disabled and having 300 grand mal seizures a week despite treatment.<sup>[14][62]</sup> Her parents learned about another child with Dravet Syndrome, who had been using a different type of medical marijuana since June 2011, and decided to try marijuana.<sup>[63]</sup> Her parents and physicians said that she improved immediately. She now follows a regular regimen that uses a solution of the high-CBD marijuana extract in olive oil. She is given the oil under her tongue or in her food.<sup>[14][64]</sup> Her parents said in 2013 that her epilepsy had improved so that she had only about four seizures per month, and she was able to engage in normal childhood activities.<sup>[14][65]</sup>

The type now named after Figi was not the first type her parents tried. As their original supply, a type called R4 that is also high in CBD and low in THC, was running out, they contacted the Stanley brothers. From the Stanleys' stock, they chose the high-CBD variety that has since been renamed to Charlotte's Web.<sup>[14]</sup> The phrase is a reference to the children's novel of the same name.

Charlotte's story has been featured on two CNN documentaries,<sup>[15][18]</sup> *The Doctors* TV show,<sup>[66]</sup> *60 Minutes* Australia,<sup>[67]</sup> and *Dateline NBC*,<sup>[68]</sup> among many other sources. An article in the *National Journal* detailing the role of several children as "uniquely powerful advocates for medicinal pot across the country" described Charlotte as the "first poster child for the issue...."<sup>[29]</sup> Her story has led to her being described as "the girl who is changing medical marijuana laws across America,"<sup>[69]</sup> as well as the "most famous example of medicinal hemp use".<sup>[70]</sup> On November 13, 2019, Charlotte was the first child featured on the cover of *High Times* magazine in her "Namesake" role as a "High Times Female 50" award nominee.<sup>[71]</sup>

### 3.4. Publicity and Demand

When Charlotte was five years old, her story was featured in the August 11, 2013 CNN documentary "Weed", hosted by Sanjay Gupta.<sup>[15]</sup> On November 24, 2013, Paige Figi was a guest on *The Doctors* TV show, where Charlotte's story was told.<sup>[66]</sup> She was also featured in Gupta's March 11, 2014 CNN documentary "Weed 2: Cannabis Madness".<sup>[18]</sup> The extract received more publicity on October 6, 2014, when *The Doctors* TV show again featured a story about usage of Charlotte's Web. The physicians called for a change of the Federal classification.<sup>[73]</sup> Sanjay Gupta has also expressed his support for Charlotte's Web on *The Doctors* TV show.<sup>[74]</sup> On the October 17, 2014 episode of the ABC TV series *The View*, Paige Figi and Joel Stanley were interviewed by Whoopi Goldberg and Nicolle Wallace.<sup>[62]</sup>

The CNN documentaries received widespread publicity and popularized Charlotte's Web as a possible treatment for epilepsy and other conditions.<sup>[14]</sup> Colorado has legalized both the medicinal and recreational use of marijuana, and many parents have flocked there with their suffering children in search of Charlotte's Web and other forms of medical marijuana.<sup>[75]</sup> In November 2013, CBS Denver reported that "[t]here is now a growing community of 93 families with epileptic children using marijuana daily. Hundreds are on a waiting list and thousands are calling."<sup>[16]</sup> In October 2014, *Time (magazine)* noted the Stanley brothers had a waiting list of "more than 12,000 families."<sup>[76]</sup> They have been termed "marijuana refugees",<sup>[16]</sup> "part of a migration of families uprooting their lives and moving to Colorado, where the medicinal use of marijuana is permitted...forced to flee states where cannabis is off limits."<sup>[77][78]</sup> In November 2014, David Nutt mentioned Charlotte's Web in the Royal Pharmaceutical Society's *Pharmaceutical Journal*, where he appealed for "the UK government [to] acts on evidence, allowing the use of medicinal cannabis and reducing barriers to its research."<sup>[79]</sup>

Families who say they have run out of pharmaceutical options have moved to Colorado to access Charlotte's Web. The demand has spurred calls for more research to determine whether these products actually do what is claimed. Amy Brooks-Kayal, vice president of the American Epilepsy Society, stated that epileptic seizures may come and go without any obvious explanation, and that Charlotte's web could cause developmental harm. She recommended that parents relocate so that their affected children could have access to one of the nation's top pediatric epilepsy centers rather than move to Colorado.<sup>[80]</sup>

The product has been described as the "country's most famous brand of CBD oil",<sup>[81]</sup> the "largest selling CBD oil in the country",<sup>[82]</sup> and the "number one brand", with 7% of the market.<sup>[83]</sup>

### 3.5. Distribution

In November 2013, Josh Stanley said that Charlotte's web was 0.5% THC and 17% CBD,<sup>[12]</sup> and that it "is as legal as other hemp products already sold in stores across Utah, including other oils, clothing and hand creams, but is illegal, federally, to take across state lines."<sup>[84]</sup> The legalities of selling the product to people who transport it across state lines is complicated, with difficulties for both the sellers and transporters. Regardless of state laws in Colorado and Utah which would allow the practice, it is still a Federal offense to transport hemp products across state lines.<sup>[85][86]</sup> In September 2014, the content was measured at 0.3% THC.<sup>[87]</sup>

### 3.6. Initial Public Offering in 2018

On August 30, 2018, Charlotte's Web Holdings, Inc. (formerly Stanley Brothers Holdings Inc.) began its launch into the stock market with an initial public offering in Canada: "The offering included a treasury issuance by the company of common shares...moreover, a secondary offering of Common Shares...for total gross proceeds of C\$115,115,000 (USD 87,598,872)."<sup>[88]</sup>

## 4. Research

The relationship between the Schedule I status of cannabis in the United States and the lack of scientific research on cannabis has been claimed by some to be directly related.<sup>[89]</sup> The situation has been described as a "catch-22" paradox: "Marijuana is restricted in large part because there is little research to support medical uses; research is difficult to conduct because of tight restrictions."<sup>[90]</sup> Sanjay Gupta has described the complex interaction between restrictive laws and lack of scientific research:

Gupta repeated throughout the evening that the "policy has outpaced the science." The states, he said, "are moving forward without waiting for the science, and the issue is only compounded by the fact that the 'policies and the laws we have in [the US] make it challenging for the science to get done."<sup>[89]</sup>

Even though the Florida "Compassionate Medical Cannabis Act of 2014" (SB 1030)<sup>[39]</sup> provides funding for research, the status of all cannabis products as illegal Schedule I drugs has limited the amount of research, with the University of Florida refusing to do such research for fear of losing federal funding.<sup>[47][91]</sup>

The interest created by the documentary highlighted a need for increased scientific research, as well as caution against "bad medicine" and raising false hopes: Ed Maa, a specialist in epilepsy, stated: "This is not going away. ...I think it needs to be studied vigorously and very quickly." He hopes to "launch a clinical trial to study the pot and its potential."<sup>[16]</sup> Physicians have called for more research to better understand the potential benefits of controlled use of medical marijuana;<sup>[1]</sup> Sharon Levy, director of the Adolescent Substance Abuse Program at Children's Hospital Boston said:

"The AAP strongly supports more cannabinoid research to better understand both how these substances can be used therapeutically as well as their potential side effects—which we may well be underestimating...[But] the AAP does not support 'medical marijuana' laws as they circumvent regulations put in place to protect patients, and children are a particularly vulnerable population."<sup>[1]</sup>

Physicians have expressed both positive interest and worry about the sudden explosion of interest in the legalization of medical marijuana and its research, admitting legalization is both "a scientist's dream or a doctor's nightmare." They fear that some parents are too open to trying anything before proper research has been conducted, and that they may be disappointed. They are "alarmed by parallels to past miracle-cure manias later proved false..." and "...wary of the heightened placebo effect in treatments involving children, when reports of progress depend on the view of parents."<sup>[92]</sup> There is also danger that "the [legalization] movement also opens the way for bad medicine...through treatments at best giving hope to the hysterical and at worst delivering damaging side effects."<sup>[92]</sup> According to Alan Shackelford, Charlotte Figi's physician: "We really don't know how it works... The cannabidiol seems to act as a neuro-stabilizer, but how? The research is minuscule on this."<sup>[93]</sup>

Orrin Devinsky, a neurologist at New York University's Comprehensive Epilepsy Center, where he will conduct clinical trials on Epidiolex,<sup>[94]</sup> a high-CBD drug from GW Pharmaceuticals, expressed his sympathy for those who do not want to wait for research results:<sup>[40]</sup>

I had a child who had failed 15 medications and drug treatments and there was nothing else to do, and they were having many seizures a day that were terribly disabling, I think it would be a very reasonable thing to do to try a high-CBD cannabis product.

He also expressed concern that the number of parents using the Charlotte's Web extract will make it harder to find children for the clinical trials, and that:

There are many more unknowns than knowns...the focus of the community—lay and scientific and governmental—should be on getting good information. That should be the real focus of what we need right now.<sup>[40]</sup>

The Epilepsy Foundation and Devinsky issued a joint statement calling for increased research and immediate access to medical marijuana, specifically naming Charlotte Figi's case. Devinsky said:

We need to make a balanced decision about compassionate use. If I were Charlotte Figi's parents and lived in Colorado I would have done exactly what they did. And as a doctor, I would gladly prescribe marijuana products for many of my patients who failed existing therapies if it were legal in my state. ... Until we have the scientific data, we should make medical marijuana available to physicians who care for people with treatment-resistant epilepsy and their patients.<sup>[95]</sup>

Due to reports that some people with Dravet syndrome seem to benefit from treatment with Charlotte's Web, an observational clinical trial was launched in September 2014 at the University of Colorado.<sup>[96]</sup> The study will run until February 2016, will focus on genetic differences between people who respond and do not respond, and attempt to determine if such genetic factors may be related to the success or failure of treatment.<sup>[97]</sup>

In January 2018, it was reported that trials with Epidiolex, a high-CBD pharmaceutical, had been successful enough that it might be "available as soon as the second half of 2018 in the United States, pending Food and Drug Administration approval."<sup>[98]</sup>

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