By Fred Gardner

In August 2013, the widely respected neurosurgeon Sanjay Gupta, MD, documented on television the dramatic seizure relief that CBD-dominant cannabis oil was affording a little girl with Dravet Syndrome, a very severe form of epilepsy. Her name was Charlotte Figi.

In the two years that followed, reports from physicians treating pediatric epilepsy patients in various contexts—including “expanded access” programs authorized by the U.S. Food and Drug Administration—have confirmed that CBD is an effective anti-convulsant.

Bonni Goldstein, MD, in California and Margaret Gedde, MD, in Colorado have each monitored the progress of hundreds of pediatric epilepsy patients. (See stories on pages 7 and 33.) More than 600 patients have been treated in FDA-sanctioned programs using GW Pharmaceuticals’ Epidiolex, a plant extract that is 99% CBD.

Slightly more than half the children using CBD-rich oil are having significantly fewer and less-severe seizures. Personalities and abilities emerge as children wean off debilitating synthetic anti-convulsants.

The side effects of CBD are generally mild; drawdown is foremost.

Why CBD-rich oil works for some patients but not for others is being pursued by researchers.

For a fortunate five to 10 percent of patients, CBD-rich oil eliminates seizures entirely. For an approximately equal number, it doesn’t help at all, or exacerbates symptoms.

Why CBD-rich oil works for some patients but not for others is being pursued by researchers. In most pediatric epilepsy cases the conditions are caused by genetic mutations. Some but not all gene-related epilepsy are amenable to treatment with CBD, and some are proving amenable to treatment with CBD plus THC and other cannabinoids.

Doctors and patients are tracking which cannabinoid-terpenoid blends are most effective in treating various conditions.

By O’S News Service

Cannabidiol varieties containing unusually high amounts of THCV —tetrahydrocannabivarin —will become available to medical users in 2016, thanks to kind fate and the pharmaceutical company GW Pharmaceuticals, which was grown in western Marin County, California, in the summer of 2015.

GW Pharmaceuticals began investigating THCV more than a decade ago in hopes that it could be useful in treating metabolic syndrome. The disorder is actually a set of symptoms—high blood pressure, increased abdominal fat, elevated blood sugar, and unhealthy cholesterol levels—that are associated with obesity, type II diabetes and heart disease.

Roger Pertwee and colleagues at the University of Aberdeen reported in 2005 that THCV blocked anandamide (the molecule made by our bodies that activates the CB1 receptor) while allowing THC to act almost unimpeded at CB1. John McPartland commented on Pertwee's finding: “It’s as if cannabis was designed as a combination remedy that simultaneously gave our endogenous mechanism a rest (shutting down anandamide), and supplemented with an exogenous remedy (THC).”

Also in 2005 the pharmaceutical giant Sanofi-Aventis had begun marketing a drug called Rimonabant—which works by fully blocking the CB1 receptor—as a treatment for metabolic syndrome. The first-ever mention of the endocannabinoid system in the Journal of the American Medical Association was a paper entitled “Effect of Rimonabant, a Cannabinoi-d 1 Receptor Blocker, on Weight and Cardiometabolic Risk Factors in Overweight or Obese Patients: RIO-North America: A Randomized Controlled Trial,” published in February 2006—about 14 years after the components of the system had been identified.

Few patients who use cannabis in treating epilepsy smoke or inhale vapor from CBD-rich flowers, although some report that inhalation after a seizure can reduce the duration of a headache.

Inhaled cannabis goes through the lungs to the brain and exerts its effects almost immediately, but the effects tend to wear off within an hour. Ingested orally, the compounds in cannabis pass through the stomach and the liver on the way to the brain. They get metabolized into slightly different compounds whose effects may take close to an hour to come on, but can last eight or nine hours.

CBD counters the mood-altering effects of THC, but as a component of the Cannabis plant, it is defined by the U.S. government as harmful and without medical use, and it remains on Schedule I of the federal Controlled Substances Act. There is an obvious gap between federal law and reality. It can be fully closed by rescheduling or descheduling the plant, and partially closed by singling out cannabidiol for descheduling.

For a slimmer waistline?

By O’S News Service

Cannabidiol may counter metabolic-syndrome symptoms...
The Road to FDA Approval
In 1998 GW Pharmaceuticals received approval from the British Home Office to develop medicines from Cannabis plant extracts containing cannabinoids other than THC that are intended by the users to be smoked. In 2000 GW sponsored a meeting in New York of the 30 patients (15% were deemed to have got an underlying inflammatory process—GW would submit the data to the FDA. A priority review would take eight months to achieve at least a 50% reduction in seizure frequency compared to baseline.

Epidiolex enabled 48% to achieve at least a 50% reduction in seizure frequency compared to baseline. mumn amount of time determined to offer accurate effectiveness measure). Epidiolex enabled 48% to achieve at least a 50% reduction in seizure frequency compared to baseline.

Over the course of 2014, physicians would conduct Treatment Resistant Epilepsy in Drug Administration Modernization Act.

The FDA then developed regulations concerning INDs for unapproved drugs. These were revised over the years, and in August 2009 FDA issued its “final rule” on “Expanded Access to Investigational New Drugs for Treatment Use.” The summary states: “Expanded access to investigational drugs for treatment use is available to inpatients in a medical institution who are not enrolled in a clinical trial, and to outpatients who are enrolled in a clinical trial, but whose consent to participate in the trial has been withdrawn, or who for other reasons do not wish to participate.”

The FDA regulations spell out criteria for establishing INDs. The IND must involve human subjects, among other things: “Chemistry, manufacturing, and controls information must be available for the drug and its formulation, and the IND sponsor must have adequate stability, purity, and strength of the investigational drug.”

In other words, FDA wants to see a high standard of testing. “Good-Manufacturing-Practices” medication—which Epidiolex is. NIDA is still providing Mis- sion Medical a supply of Epidiolex for the surviving beneficiaries of the old, informal IND program. Those cigarettes would not be approved as a treatment under the current regulations.

The FDA requires “Pharmacology and toxicology information adequate to conclude that the drug is reasonably safe at the dosage and route of administration proposed for the treat- ment use.” When GW was approached by the par- ents of epilepsy patients in late 2012, the company already possessed extensive preclinical data—five-and-a-half years’ worth—establishing the safety of its CBD product, as well as information the FDA would require concerning its chemistry, manufacturing, controls, pharmacology, and toxicology.

In December 2012 GW agreed to provide purified CBD and the requisite data for single-patient INDs conducted by epilepto- logists MD at the University of Missouri, Kansas City, and Orrin Devinsky, MD at NYU School of Medicine.

In October 2013 GW supported and NYU sponsored a meeting in New York of epilepsy specialists interested in conducting clinical research with purified CBD in the United States. Devinsky described dra- matic benefit provided to his initial patient by CBD treatment, and his plans to conduct an IND treatment program at NYU. Many of the questions and comments that followed the presentations indicated that if the INDs would indeed allow the company to provide Epidiolex to the parents, even though it was an investiga- tional drug. By January, 2014, INDs conducted by Devinsky (one patient), MD at Children’s Hospital of Missouri, and Devinsky et al. reported. Nineteen percent of all patients and 16% of Dravet patients were seizure-free after 12 weeks. Those patients who were seizure-free in week 24 showed no fail- off in effectiveness. “Randomized controlled trials are war- ning of some researchers concluded, “and we are pleased to report that these are not ongoing.”

In the spring of 2015 GW commenced a placebo-controlled clinical program—one in Dravet syndrome and one in Len- nons-Gastaut syndrome. Both of these “pivotal” trials are designed to sup- port a New Drug Application with the FDA by mid-2016.

Conditions such as Dravet Syndrome and Lennox-Gastaut Syndrome that affect a very small subset of the population—under 200,000 in the U.S.—are designated “orphan diseases,” and treatments devel- oped for them are referred to as “orphan drugs.” Most orphan diseases are the result of genetic mutations.

The Orphan Drug Act of 1983 conferred tax credits on any company that spent money on research on pharmaceutical companies willing to develop drugs for which the market is too small.

GW Pharmaceuticals sought and was granted orphan-drug status for Epidiolex as a treatment for Dravet and LGS. One of the benefits of being awarded orphan-drug status is the right to combine phase 2 and 3 clinical trials. The two phase 3 studies—clinical trials—are taking place at various institutions within the U.S. and in other countries. These studies involve patients adding Epidiolex to their regimen of anti-epilepsy drugs for a 14-week randomized, double-blinded treatment period. Results will be reported in early 2016.

Epidiolex, an extract of the Cannabis plant that contains cannabidiol (CBD), was first approved by the British Home Office to treat seizures caused by Dravet Syndrome in 2011. By mid-2016 Epidiolex will have been approved by the FDA for use in Dravet and Lennox-Gastaut Syndrome. Epidiolex contains an equal mix of CBD and THC—two of the main active ingredients in the Cannabis plant. GW is one of a number of companies that have recently turned its attention to the Cannabis plant, seeking to develop medicines from it. GW is also working with the University of Mississippi, which has the only permit to cultivate Cannabis plants for research purposes in the U.S. GW is also conducting research at hundreds of sites as of October 2014.

GW’s flagship product Sativex—which contains THC and CBD and THC was the first plant-derived cannabinoid medicine to win approval from regulatory authorities. An extract formulated for sprays, Sativex has been approved in 27 countries (starting with Cana- da in 2005) for treating pain and spasticity in multiple sclerosis patients. In recent years GW has been testing vari- ous formulations and providing CBD to scientists conducting preclinical studies in animals. GW supplied Ben Whalley and colleagues at the Centre for Integrative Neuroscience and Neurodynamics, University of Reading, who used mouse models to study the effects of CBD. The team found that CBD and another cannabinoid, CBDV, exert anti-seizure and anti-inflammatory effects, and continue to the attention of families in the U.S. who had loved ones with epilepsy.

In late 2012 some American parents contacted GW in hopes of obtaining CBD.

“Expanded Access” Physicians, patients, and parents know that currently available anti-epilepsy drugs (AEDs) are detrimental to cognition and longterm development. CBD is, way milder than conventional anti-convulsants in terms of side-effects.

In late 2012 some American parents contacted GW in hopes of obtaining CBD. They were desperate to get Epidiolex to the physicians treating their chil- dren under the Food and Drug Administra- tion’s “Expanded Access” IND program. GW had been working closely with the FDA in connection with Sativex, looked into the IND option and decided the expanded access INDs might indeed allow the company to provide Epidiolex to the parents, even though it was an investiga- tional drug. By January, 2014, INDs conducted by Devinsky (one patient), MD at Children’s Hospital of Missouri, and Devinsky et al. reported. Nineteen percent of all patients and 16% of Dravet patients were seizure-free after 12 weeks. Those patients who were seizure-free in week 24 showed no fail- off in effectiveness. “Randomized controlled trials are war- ning of some researchers concluded, “and we are pleased to report that these are not ongoing.”

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A drug that is beneficial in treat- ing the most severe forms of epi- lepsy is likely to be beneficial in treating most seizure disorders. The company also plans a clinical trial of Epidiolex in other pediatric epilepsies, starting with Tuberous Sclerosis Complex (TSC), a genetic disorder that causes non- malignant tumors in the brain and other organs, and affects some 50,000 patients in the US. Approximately 60% of TSC patients have treatment-resistant seizures. All five such patients in the expanded ac- cess program were treated by Epidiolex, it was reported at the American Epilepsy So- ciety’s annual meeting in December 2014. Another condition for which GW has proved beneficial in animal studies —and for which Epidiolex has been given or- phan drug status— is Neonatal Hypo-oxic-Ischemic Encephalopathy or NHIE (brain dam age caused by oxygen deprivation dur- ing delivery).

Children’s brains are very plastic and can usually work around issues, but if you’re having continuing seizure-related injury, that ability will be dampened. We’re hopeful from the pre- clinical work that cannabinoid will address a number of these different issues, not just one.
In March 2015 GW was issued a US patent for CBDV in the treatment of epilepsy

In 2014 GW completed a Phase I clinical trial of its CBDV product candidate, GW420014. Having established safety and tolerability, they conducted a study of CBDV in people with focal seizures (vs placebo). Next came a Phase 2 study in adult patients with epilepsy. In March 2015 GW was issued a U.S. patent for CBDV in the treatment of epilepsy—"specifically for the control of generalised or temporal lobe seizures," according to a statement by the company.

James Brodie had laid out GW’s commercial strategy in an ICBS presentation. By developing extracts and natural compounds with specified ratios, he said, "you can form a matrix of intellectual property that will be safe. It is our belief and the belief of our commercial partners that you cannot genericize Sativex."

In May 2015 GW moved its corporate headquarters from the UK to San Diego, signifying a focus on the US market and heightening the fears of many small-scale cultivators and their activist allies that GW will move against them in due course. Alice O’Leary Randall asks, "Will the feds use the inevitable approval of Epidiolex as a chip in the game to get into legal states, all to protect the copyrights and patents that GW Pharmaceuticals and the federal government hold on CBD?"

O’Shaughnessy’s posed her question to GW officials: how and under what circumstances might they assert the company’s intellectual property (IP) rights? Nobody wanted to be quoted by name. The responses included:

- Patenting products is standard procedure in developing pharmaceuticals, necessary for "freedom to operate" conferred by regulators.
- IP rights would most likely be asserted if the following was true:
  - GW was not the first to discover and develop the substance.
  - It was a new, unique, and non-obvious substance.
  - GW was able to show that the substance was safe and effective in a use that was new, unexpected, and non-obvious.

In late 2008 an Oakland start-up, Steep Hill, began testing cannabis plants for cannabinoids, with an eye to testing in storage.

From 2009 through 2012, very few dispensary operators were willing to stock cannabis that was not psychoactive.

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Martín Lee and I arranged with Addison Demura and David Lampach at Steep Hill and Harborside’s buyers—to be put in contact with the growers if and when any samples were found to contain 4% or more CBD. About one in 650 samples turned out to be CBD-rich by our arbitrary definition.

In February 2012 Paige reported that they had found a dropper of oil that was effective. It had been made by the Stanley brothers of Colorado Springs. The Stanleys had launched their "Indispensary" in 2009 and added a second outlet in 2011. They were not pro-cannabis activists. They knew that marijuana was safe and effective, having seen a family member get significant relief from it as he was dying from cancer. And, as Paige says, she had "bought and lab tested thousands of dollars of medical cannabis. Oil from the high-THC strains helped with some ailments and comorbidities (sleep, appetite, autism, rage, etc.) but increased her seizures. One strain I found was working but they only had a few weeks’ worth of supply. When abruptly stopped, seizures increased."

In 2011 O’Shaughnessy suggested that GW’s research into the medical benefits of cannabidiol was reported in O’Shaughnessy’s, starting with the first issue in 2003. For years pro-cannabis doctors and their patients followed the news covetously, wishing that they, too, could investigate the medical uses of CBD. But without an analytic lab testing the contents of Cannabis plants, none containing CBD could be identified. Experts predicted that no appreciable amount of CBD would remain in a plant population which, for many generations in California, had been bred to maximize psychoactivity. In late 2008 an Oakland start-up, Steep Hill Lab, began testing cannabis brought by growers to Harborside Health Center for mold and THC and CBD content (also for CBN, cannabinol, a breakdown product of THC that was thought to indicate time in storage).

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CBDevelopments from previous page

Bear in mind that a drug that is beneficial in treating the most severe forms of epilepsy is likely to be beneficial in treating most seizure disorders.

The topic of rescheduling specific cannabinoids was carefully broached in a recent article in the New England Journal of Medicine (September 10, 2015) by Samuel Friedman and Ortin Devinsky, two of the epileptologists treating patients with Epidiolex. Relaxation of the regulatory status of cannabinoid-derived drugs, especially those containing a high proportion of non-psychoactive cannabinoids, for which the potential for abuse is low, could help to accelerate scientific study, they wrote.

They describe the work that has been done to date with Epidiolex, which they describe as 99% cannabidiol and less than 0.1% THC. They note that randomized clinical trials are underway for the treatment of Dravet’s syndrome and Lennox-Gastaut syndrome. "No evidence exists that the antiseizure effects of cannabidiol are limited to the treatment of these conditions," they add.

While acknowledging the evidence that THC has anti-convulsant effects, Friedman and Devinsky state that "Cannabis-based treatment with THC may have irreversible effects on brain development," and, as it were a proven fact: "With longstanding use there is a risk of addiction, which occurs in approximately 9% of long-term users."

Friedman gets consulting fees from Marinus Pharmaceuticals, Eisai, SK Biopharmaceuticals, Upsher-Smith Laboratories, and Pfizer. Devinsky gets grants from GW Pharmaceuticals and Novartis. Their NEJM article concludes with an oath of allegiance to the FDA approval system and a swipe at an alternative approach to CBD distribution as a dietary supplement.

"Despite the surrender of another and the approval of medical cannabis by many state legislatures, only double-blind, placebo-controlled, randomized clinical trials in which consistent preparations of one or more cannabinoids are used can provide reliable information on safety and efficacy. The use of medicinal cannabis for the treatment of epilepsy could go the way of vitamin-mineral and nutritional supplements, for which the science never caught up to the hype and was downgraded after uncontrolled, sensational testimonials, and clever marketing. If randomized clinical trials show that specific cannabinoids are unsafe or ineffective, those cannabinoids should not be available. If studies show that specific cannabinoids are safe and effective, then those preparations should be approved and made readily available."

The image of CBD being distributed as a nutraceutical was not hypothetical. It was a reference to the Charlotte’s Web phenomenon.

"Charlotte’s Web"

GW Pharmaceuticals’ research into the medical benefits of cannabidiol was reported in O’Shaughnessy’s, starting with the first issue in 2003. For years pro-cannabis doctors and their patients followed the news covetously, wishing that they, too, could investigate the medical uses of CBD. But without an analytic lab testing the contents of Cannabis plants, none containing CBD could be identified. Experts predicted that no appreciable amount of CBD would remain in a plant population which, for many generations in California, had been bred to maximize psychoactivity. In late 2008 an Oakland start-up, Steep Hill Lab, began testing cannabis brought by growers to Harborside Health Center for mold and THC and CBD content (also for CBN, cannabinol, a breakdown product of THC that was thought to indicate time in storage).

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In December 2012 Paige linked up with Jason David, a former Navy SEAL and Iraq veteran with Special Forces) who was researching cannabis and epilepsy. Seven parents “chatted, shared info, looked into research together,” is how she describes it. At this point, Paige says, she had “bought and lab tested thousands of dollars of medical cannabis. Oil from the high-THC strains helped with some ailments and comorbidities (sleep, appetite, autism, rage, etc.) but increased her seizures. One strain I found was working but they only had a few weeks’ worth of supply. When abruptly stopped, seizures increased.”
became that cannabis has a vast range of applications. But they hadn’t seen anything like Charlotte Figi’s sudden and sustained improvement.

The Stanleys guaranteed Paige a regular supply of oil from the super-effective plant, which they renamed “Charlotte’s Web.” It typically grew to a height of four feet and had a CBD-to-THC ratio greater than 20-to-1. Some in Colorado assumed it had been bred from a CBD-rich strain called R4.

Word of Charlotte Figi’s progress circulated online and parents of epileptic children began contacting the Stanleys with applications. In July 2012, Paige, Mandy Stanley (Joel’s wife), and Heather Jackson – whose son Zaky had spastic quadriplegia caused by a degenerative condition called shaking chimp syndrome – traveled from both southern California and northern Colorado to see the Stanleys. Paige watched as Joel’s new team expanded the lab facility, which had consisted of about 200 square feet. Joel explained that Charlotte’s Web oil was grown legally as hemp.

Heather Jackson moderated the Realm of Caring conference, which usually alternates between Denver and Washington, D.C. The event attracts professionals and patients from around the world. Joel described the production cycle. “The plants are harvested and dried, for research purposes. The dried plant is then ground, and there’s a 1:1 ratio of THC to CBD. It’s then ground further and mixed with coconut oil to make the final product.”

Heather Jackson reminded her audience that while there are a number of clinical studies ongoing, there have been no large-scale randomized trials of Charlotte’s Web or any other form of medical cannabis.

We’re just pushing and pushing and pushing, and we’re not going to stop until Charlotte’s Web oil is legal in every state. We care about all of these patients. I travel every week and I’m for everybody. This is not just about Paige. It’s about some of the last people trying to push, this is about a socialized medicine.”

Paige Figi was too young to know, I gleaned in a later conversation, that the politicians whose support she seeks would find the term “socialized medicine” slightly more offensive than motherf**ker—Paige had used those words, technically, to describe to her and Realm of Caring’s principle that “no one should be denied Charlottes Web’s benefits simply because they’re typically from rural areas.”

The fear, said Paige, “isn’t you going to prison, it’s CPS taking your child from you. Until the scheduling is changed or de-scheduled, it’s going to be just a little bit too easy just to say, ‘We’re going to go in and say it should be for this...’ ”

The Realm of Caring conference in Denver not only provided a venue for medical marijuana advocates to celebrate their hard-fought victories. It also served as an opportunity to inform those interested about the latest research and medical cannabis products. The conference addressed a wide range of topics, from the latest advances in medical cannabis research to the legal status of medical cannabis, and provided a platform for patients, doctors, and advocates to share their experiences and insights. The conference was a place where people came together to discuss the future of medical cannabis and the steps needed to make it accessible to all who could benefit from it. It was a testament to the power of community and the importance of bringing attention to the needs of those who rely on medical cannabis for their health and well-being.
November 2014: The Shipping News

The harvest in Wray turned out to be a bumper crop, but in early November, citing the advice of counsel, the Stanleys announced that they would not be shipping CW oil to patients in states other than Colorado or California. Paige Figi, interviewed at the time, said, “We’re trying to pass the federal bill so we can ship this, and trying to pass state laws so patients can receive it.”

Nothing in Figi’s background prepared her to become a political organizer (although she did take a few pre-med courses at Colorado State). “Ten thousand bills are introduced and 1% get passed. Many are just to get media attention for their cause. That’s what we’re doing in this way.”

Charlotte, at age eight, has osteoporosis from long-term use of pharmaceutical AEDs; she has broken each of her legs in the past year. Her mother attributes her frail bones to “permanent side effects of seizure drugs,” a condition she calls her “giant lambs.”

Charlotte’s twin sister Chase has handled the family tragedy “in the most stand-up way,” says Figi. “She is Charlotte’s caregiver.” Paige Figi was the “most strong kid who has had to deal with a lot.” And she has gotten to see Charlotte improve.

The siblings of seriously ill children “have more responsibility,” Figi observes. “They have loss of innocence at a young age. They get to see how you [parents] parent.”

Matt Figi now works in Afghanistan as a contractor for the U.S. military. Paige says that Charlotte was “called home” butucs on emergency leave” made a career in a Special Forces impossible. “He didn’t want to go into the Regular Army so he got out and now he’s doing what he was deployed more now than when he was in the military.”

“Do Adolescents and Young Adults with Inflammatory Bowel Disease Benefit from Use of Marijuana?” Principal investigator: Edward J. Hoffenberg, Department of Pediatrics, Children’s Hospital of Colorado. The specific cultivars for Charlotte’s Web Hemp Oil are only grown in Colorado, he adds. Extraction is by alcohol per the original process. “Most RoC clients prefer the original formulation. We don’t even grow it out from seeds, we keep growing from clones and tissue culture.”

The retail price of CW Hemp Oil was $10/milligram as of November 2015. RoC members get a code which discounts it by 50%.

CBD-rich plants grown by the Stanley Brothers in Kentucky will go into other CBD products such as topicals, less concentrated tinctures, and vape oils. The company keeps up with the technology for bigger batch sizes. Two supercritical CO2 extraction machines were used in 2014. In 2015, the company said, and one of extracting roughly 620 lb of pure CBD per week* — is being delivered.

As for relations with the federal government, Dr. Michael Pollan, director of the Multidisciplinary Association for Psychedelic Studies (MAPS) says, “The biggest thing is that the FDA is not interfering.”

The Uruguay connection

In 2014 the Stanley Brothers arranged a partnership with the first Uruguayan farmer licensed to grow hemp. Their plants will go into the ground in December 2015 — early summer in the Southern Hemisphere. (The 2014 presidential election in Uruguay was in February, a referendum on legal marijuana, which was opposed by the center-right candidate. Left-leaning Tabare Vazquez, a 58-year-old, pro-cannabis oncologist, won with a 53.40 margin.)

Uruguay allows hemp to contain up to 1% THC, which Joel Stanley calls “a significant advantage for hemp farmers. You are continued on page 45
Paige Figi wants you…

Paige Figi has been lobbying Congress to pass the Charlotte’s Web Medical Access Bill of 2015, which was first introduced in 2014 by Rep. Scott Perry of Pennsylvania. This interview was conducted by managing editor Alison O'Shaughnessy (no relation to the Colorado Senator).

O’S: Where do things stand with the Charlotte’s Web bill?

Paige: The Senate version of the bill was introduced by Cory Gardner of Colorado. Slight language differences, but the bill mirror each other when they get through. We have the support of Orrin Hatch of Utah. He wrote the Dietary Supplement Act in ’94. This bill puts CBD as a dietary supplement.

O’S: How does the Gardner CBD bill relate to the Rand Paul/Cory Booker/Kristen Gillibrand bill?

My bill is just a CBD and agricultural hemp de-scheduling bill.

Figi: The CARERS Act is a broad, very comprehensive bill … My bill, the Perry bill, is a component of their bill. Their bill has multiple components. One of them is to de-schedule CBD. And my bill is just a CBD and agricultural hemp de-scheduling bill. That component in the plant, is removed from the Controlled Substances Act entirely. And agricultural hemp is removed from the Controlled Substances Act entirely. Separating those two things out across the umbrella of the whole cannabis plant that is on Schedule I.

O’S: Don’t you think supporting the Charlotte’s Web bill will give some politicians cover not to vote for the broader bill?

Paige: Our bill was there before there was a CARERS Act. There are politicians who will never, while they’re in office, ever vote for a comprehensive medical marijuana bill. They just will never do it. They would have never allowed for a hemp agricultural bill if not for Charlotte’s Web — even though it’s benign and harmless, they still would never sign onto it and let it pass. But I try and only travel when my husband is not in Afghanistan.

O’S: He’s a contractor now. For so it’s only the bare, minimum that I travel. If I can get a meeting. I only meet with potential sponsors and leadership — really critical meetings. I don’t just go chasing down the halls of the Senate and lobby like crazy. I only set up these private meetings where I live and I try to be where people are so very efficient is what I’m saying, and I don’t like to be away from my children.

O’S: Who is against your bill?

Paige: There are a large, a well-funded lobby against this bill. I shouldn’t have said our chances are 100%. Pharmaceutical interests are lobbying against this bill, saying this should not exist as a dietary supplement, wait till it’s available from the pharmaceutical industry and paid for by insurance. It’s going to be a gold albatross and push them all, we could be a very, very scary force. I know there’s a lot of dissen- sion, but there’s a majority now. If you poll more than a hundred, there’s a common question that people fear for their career might be swayed — “treat it like a pharmaceutical” might seem a quick, easy out if you’ve got a two year old.

We say: Treat CBD like Vitamin C — a dietary supplement that shouldn’t be owned and patented and pharmaceuticalized. It can be — that process can happen simultane- ously, however long it takes — but it doesn’t have to be.

There are legislators who have said, “I don’t have anyone in my district that has epilepsy.”

The legislators need to hear from people. There are legislators who have said, “I don’t have anyone in my district that has epilepsy.” And I’m like “You have one percent of your district just with epilepsy alone!”

They’re just not hearing from anybody. We could put a dugger through the heart of a pharmaceutical company, because we have numbers and we’ve got an army.

O’S: Let me ask you a few questions. What are the odds of Colorado’s index of patients slowed down now that you’re able to ship to so many other states?

Paige: There are still a lot of refugees who come here. It’s THC and THCA. And they come here for CBD — even Charlotte’s Web — because even though they can get it shipped, they can’t go to the hospital in Texas or Idaho and get them there. They’re on Schedule I substance. They can’t tell them at school. They worry about local law en- forcement because they are still illegal in their state. So there’s still refugees coming here. We’ve lost a lot of advocacy for the coalition because people are like “It’s shipped to my door now. I don’t need to work to change the laws.” I’m hoping they realize this isn’t done until we federally amend the scheduling.

O’S: How did you finally decide to ship across state lines?

Figi: The Stanley Brothers decided to

Hemp should be an industry in this country. Why import it?

O’S: Do you have any allies?

Figi: The Coalition for Access, a 501c(4), is platform for all the voices backing this bill. Everyone told me it takes money to pass a bill and I didn’t believe it because everybody knows that CBD helps these kids — it’s not controversial. I’m sad to say that it’s your money. There are very few peo-ple who don’t want this to pass, but they’re heavily funded. We have public opinion but no funding.

Figi: I’m a leader in each state that collects advocates. If it’s a large state like Texas and Colorado, two or three. And they all help the advocates that contact us either to do media, go to DC, or when their legislator is on recess, ask them to co-sponsor it.

So these parents go push our narrow mes- sage — they show pictures of their children wearing helments — and reach out and help drive up that advocacy number, drive up the co-sponsorship number.

Some economies get sold to pro-gressives as “a first step” towards bigger reforms. And then they turn out to be all we get; it’s just a fast step, not the first. So there’s reason to fear that a CBD-only bill could take the wind out of the sails of the medical marijuana movement, like some people say Obama care took the wind out of the sails of Single Payer Healthcare.

But this situation could be different be-cause so many people are educated about CBD and know that THC is beneficial and in many cases necessary. And especially if you, Paige Figi, are committed to keep pushing for the CARERS Act.

Figi: Absolutely. And why make the farmers wait? The farmers don’t care about THC. They want this crop. Hemp should be an industry in this country. Why import it? And the kids need CBD. Why is it ethical to make them wait?
ASA pushing the CARERS Act

Steph Sherer, Executive Director of Americans for Safe Access, helped educate Kirsten Gillibrand of New York and Cory Booker of New Jersey on the need for changes in federal law to make marijuana available as a medical and adult-use drug. “It’s too hard to get anything, and we can’t do anything without federal approval,” said Sherer. “We need to find a way to help get people better.”

Some backers of the CARERS Act fear that bills legalizing CBD will enable pharmacists to dispense medical marijuana for free. “The federal government has finally accepted that there is medical use for marijuana,” said Mike Liszewski, executive director of the Center for Medicinal Cannabis Policy.

What it would do

By Mike Liszewski

On March 15, 2015, U.S. Senators Cory Booker (D-NJ), Rand Paul (R-KY), and Kirsten Gillibrand (D-NY) introduced the Compassionate Access, Research Expansion, and Respect States (CARERS) Act – the first comprehensive piece of medical marijuana legislation to be introduced in the U.S. Senate. Americans for Safe Access was honored to have played a role in shaping the direction of the bill, and many of the patient-focused issues we brought up were addressed in the final legislation.

The bill’s introduction comes just a few months after passage of the Rohrabacher-Farr Amendment, which was guided through the conference committee by the leadership of Senator Mikulski (D-MD). The Rohrabacher-Farr Amendment arguably should have defunded the prosecution of the Kettle Falls Five by the US Attorney for Eastern Washington, but the decision of the House to dismiss shows that there is some legal dispute as to whether Rohrabacher-Farr Amendment will end federal interference for anyone acting in compliance with State law. There is no question that such prosecutions would end under the CARERS Act, which states:

“Notwithstanding any other provision of law, the provisions of this title relating to the production, possession, distribution, dispensation, administration, laboratory testing, or delivery of medical marijuana.”

Prior to introduction of the CARERS Act, many Senators have avoided taking an official position on medical marijuana because there was no legislation in the Senate on the issue. Now Senators must confront it.

Patient advocates and other stakeholders have an opportunity to discuss each of the bill’s issues in a substantive way. Rather than decry any perceived shortcomings, patient advocates can make strategic use of their time lending support to help get the bill heard before the Senate Health, Education, Labor, and Pensions Committee and offering suggested amendments to improve the bill.

To help better understand the bill, below is some section-by-section analysis (skipping Section 1, which is simply the title of the bill):

2. Federalism in Drug Policy

This is the section quoted above. It allows all state-legal medical marijuana conduct to continue to exist without any federal interference. Unlike the Department of Justice’s August 2013 Cole Memo or even the Rohrabacher-Farr Amendment to the DPPA budget, this protection is both binding and permanent. ASA was successful in making certain that testing labs were included among producers and dispensaries. The exemption from the Controlled Substances Process and the NIDA monopoly on the marijuana businesses. It would explicitly remove the Public Health Service Review. This section was inspired by a similar section in the 2014 vote in Florida, in which a ballot initiative to legalize medical marijuana (the medical/adult-use businesses would be removed from the Public Health Service Review.

4. Banking

The banking section of the bill used Rep. Perlmutter’s HR 2652, the Marijuana Access to Banking Act of 2013, as its basis. The provision would allow anyone acting in conformity with their state marijuana laws to be able to access banking services. This section would exempt banks from filing suspicious activity reports on marijuana businesses. It would explicitly forbid the federal government from penalizing marijuana businesses or incentivizing banks to discriminate against legal marijuana businesses. ASA also urged the bill sponsors to make sure that the two biggest barriers to medical marijuana research in the US were addressed, the Public Health Service Review Process and the NIDA monopoly on the supply of available research marijuana. The Obama Administration has already removed the Public Health Service review. The CARERS Act would end the single source monopoly for federal marijuana made available for FDA-approved research. This will help ensure that a greater variety of marijuana is available to help foster meaningful research in the U.S.

7. Research

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5. CBD Determination by States

This section was inspired by a similar provision in the S. 134, Industrial Hemp Farming Act of 2015, which had a safety valve provision for states that allow more than 0.3% THC in their CBD laws. ASA provided the Senate offices with language that will protect the patients in states that allow 0.5% to 5% THC in their CBD laws, such as Alabama, Florida, Iowa, Missouri, South Carolina, Tennessee, and Virginia.

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3. Rescheduling of Marijuana

The rescheduling portion of the bill is probably the section that will get the most criticism from patient advocates and others. While placement in Schedule II does not appear to be appropriate based on its widespread medical acceptance and lower abuse potential than other Schedule II substances like cocaine and methamphetamine, it would show that the U.S. government has finally accepted that there is medical use for marijuana.

Placement on Schedule II could also potentially open up health insurance coverage for medicinal marijuana therapy, but that would not happen automatically. There are some who have expressed concerns that if marijuana were placed in Schedule II that it would mean pharmacies would have to take over distribution and that pharmaceutical companies would take over production.

However, Section 2 of the bill, complete exempt states program from the CSA, so they could continue to operate regardless of any potential implications of Schedule II status.

4. Exclusion of Cannabinoid from Definition of Marijuana

This concept of this section of the bill similar to Rep. Scott Perry’s HR 5226 from the 113th Congress, but has been slightly modified. This language would completely remove derivatives of marijuana with less than 0.3% THC content from the CSA, which would enable transportation of high-CBD extracts across state lines.

States that have not already passed full medical marijuana laws or CBD-only laws would still need to pass such laws for protections to be complete in those states. It is a fairly safe assumption that most, if not all remaining states without CBD protections would adopt such laws in the wake of federal passage.

8. Veterans

ASA also urged the Senate sponsors to include a section that would allow VA doctors to fill out state medical marijuana recommendation forms.
Hemp closer to indica

Sativa | Indica Genotypes Quantified

It has long been assumed that the difference between plants considered by cultivators to be Cannabis sativa and plants considered C. indica was the result of differences in the genes determining cannabinoid content. But the differences are spread throughout the genome, according to a new study by Canadian plant geneticists.

The researchers analyzed 81 marijuana and 43 hemp samples and found that “marijuana and hemp are significantly differentiated at a genome-wide level, demonstrating that the distinction between these populations is not limited to genes underlying THC production.”

The study, published August 26 on PLOS1, developed “evidence that hemp is genetically more similar to C. sativa type marijuana than to C. sativa strains.”

The authors concluded that there is a “moderate correlation between the genetic structure of marijuana strains and their reported C. sativa and C. indica ancestry.” They also found that “marijuana strain names often do not reflect a meaningful genetic identity” — confirming what Dr. Jeffrey Raber and other chemists have concluded.

The reported ancestry of the 124 plants analyzed was determined via online database searches, seed companies and licensed cultivators. Co-author Darryl Hudson (DDC Solutions in Ontario) identified the identity of 26 strains for which no online information was available. Only three strains were found to actually be 100% Sativa: Dr. Grimspoon, Neville’s Haze, and Super Silver Haze.

The graphic at right lists the strains tested and the ratio of Sativa (left part of each horizontal bar, in red) to Indica genetics (right hand part, blue). How inaccurate the commonly used names can be is illustrated by the total absence of Sativa genetics in Durban Poison, Jamaican Blue Bread and La Riena de Africa — all reputed to be 100% Sativas.

Lead author Jason Sawler is with Ananda Labs in Vancouver and Dalhousie University’s Agriculture Faculty. The study was planned by Sean Myles, also of Dalhousie, and Jonathan Page of Anandia Labs and the University of British Columbia Botany Department.

In 2015 the Tennessee Department of Agriculture licensed 47 farmers to plant hemp on 1,959 acres and allowed importation of 38,180 pounds of seed for them (almost all from Canada). But, as reported by Clay Duda in the Knoxville News-Sentinel, “One shipment that arrived in Memphis was sent back to Canada after the carrier, FedEx, discovered the package contained hemp seed, which the company considered a narcotic. Other delays were attributed to the DEA slow-walking necessary paperwork to import the seeds.”

So instead of planting in April and May — when fast-growing hemp would have shaded out weeds — Tennessee farmers were planting in June and July and their Cannabis had to compete with weeds. (The University of Tennessee had a one-acre hemp plot on which 15 herbicides and pesticides were tested.)

FedEx — but not the DEA — was also responsible for blocking hemp seed deliverables to Canada. The USDA licensed 7,657 acres of hemp in 2015. Some 2,900 acres were planted, availability of seeds being the main limiting factor. The Colorado’s Agriculture Department also licensed 57,000 feet of space for hemp cultivation. Most of the crops are going towards CBD production. “Colorado tested 52% of the seeds this year and only 8% were above 0.3% THC,” Steenstra says. Plants in only one field were found to contain more than 1% THC. “Given the lack of certified seed, that level of compliance is really quite good,” Steenstra observes.

Bill Polyniak is a Kentucky farmer who considers the hemp program “an absolute success.” Originally involved because he has a son with epilepsy, Polyniak now sees hemp as a way to “revitalize” individuals’ lives and the overall economy. In 2015, Polyniak grew hemp in three Bluegrass Country locations — two dedicated to CBD oil production, one to seeds for planting in the future. “I’m thinking about 2025,” he says. “These children are growing up with oil all around them.”

After a CO2 extraction process in Kentucky, a portion of Polyniak’s CBD-rich oil is trucked to South Carolina, where it is further refined, bottled and sold by a company called Palmetto Harmony — “created after a collection of parents with special children ran out of options using modern medicine,” the website says. Palmetto Harmony CBD products are sold at healthfood stores in South Carolina.

Polyniak and his wife have developed their own brand of CBD-rich oil, “Genesis Blend,” available through their Kentucky Cannabis Company & Bluegrass Hemp Oil websites. The 2014 harvest enabled Polyniak to get the price per milligram of CBD below a dime. The 30 ml bottle holds 300 milligrams of CBD oil and provides 10 milligrams per full dropper. (The dropper contains 30 milliliters.) A stronger extract of 1,500 mg per bottle provides 50 mg of CBD per dropper-full. Both strengths are available in larger 4 ounce bottles. Polyniak has applied for licenses to cultivate 20 acres of hemp in 2016. The goal of the breeding program is to maximize CBD content, seed production and fiber quality and quantity.

When Hemp Reigned in Kentucky

In 1900, Macmillan published “The Reign of Law: a tale of the Kentucky Hemp Fields,” by James Lane Allen. If published nowadays it would probably be shelved among the romance novels. The heroine, Gabriella, comes from a wealthy family (even though they’ve lost their slaves). She is a devout young woman, takes the Bible literally, “The hero, David, is the son of a devout hemp farmer. David goes off to college and learns about evolution. He comes home, gets expelled from the church founded by his great-grandfather, and feels the wrath of his father and the disapproval of his family.”

In the first chapter, “Hemp,” it is a floral passage to its subject. Some excerpts follow:

The Anglo-Saxon farmers had scarce conquered foothold, stronghold, freehold in the Western wilderness before they became something — with the appearance of Virginia, with remembrance of dear ancestral Britain...

Hemp in Kentucky in 1782—early landmark in the history of the soil, of the people. Cultivated first for the needs of a family, and seldom elsewhere, for twine and rope, towel and table, sheet and shirt. By and by for cabin and clearing only; not for tow-homespun, fur-clad Kentucky long外套. To the north had begun the building of ships, American ships for American arms, for American farms, for a nation which Nature had herself created and had distinguished as a sea-faring race. To the south had begun the raising of cotton. As the great period of shipbuilding went on — greatest during the twenty years or more ending in 1860; as the great period of cotton-raising and cotton-baling went on — never so great before as that in the same year — the two parts of the nation looked equally to the one border plateau lying between them, to several counties of Kentucky, for most of the nation’s hemp.

It was in those days of the North that the CONSTITUTION was rigorously with Russian hemp on one side, with American hemp on the other, for a patriotic test of the superiority of home-grown, home-preparedibre; and thanks to the latter, before those days ended with the outbreak of the Civil War, the country had become second to Great Britain alone in her ocean craft, and but little behind that mistress of the seas. So that in response to this double demand for hemp on the American ship and hemp on the southern plantation, at the close of that period of national history on land and sea, from those few counties of Kentucky, in the year 1859, were taken well-nigh forty tons of the well-cleaned bast.

What history was wrought in those years, directly for the republic, indirectly for the world! What inappreciable marks it left on Kentucky itself, land, landowners! To make way for it, a forest the like of which no human eye will ever see again was felled, and with the forest went its pasture lands. The waters of Kentucky, those long lystone terraces connecting the towns and villages with the farms — they were early made necessary by the hauling of the hemp. For the sake of it slaves were perpetually being trained, hired, bartered, lands perpetually being bought and sold; fortunes made or lost. The advancing price of farms, the westward movement of poor families and consequent dispersion of the Kentuckians over cheaper territory, whither they carried the same passion for the cultivation of the same plant, — thus making Missouri the second hemp-producing state in the Union, — the regulation of the hours in the Kentucky cabin, in the house, at the rope-walk, in the factories, — what phase of life was unaffected by the pursuit and fascination of it. Thought, care, hope of the farmer oftentimes throughout the entire year!
Cannabinoid-laden substance is then refined in myriad ways. CBDevelopments supply “close to 250 kilograms” of CBD from its production facility in San Diego. It is then processed according to its wishes. In 1994 he grew hemp at the USDA’s facility in San Diego. As explained by Chris Boucher, the oil is refined and concentrated to make it suitable for human consumption.

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