

# Epilepsy & Behavior publishes study showing cannabis reduces seizure frequency, severity

The NAS Report was soon out-of-date with respect to epilepsy, thanks not just to publication in May of GW Pharmaceuticals' Epidiolex data in the *New England Journal of Medicine* by Devinsky et al, but also to the publication in *Epilepsy & Behavior* (May 2017) of a paper by Drs. Dustin Sulak, Russell Saneto, and Bonni Goldstein entitled "The current status of artisanal cannabis for the treatment of epilepsy in the United States."

Goldstein reported on 225 patients with intractable seizures seen at her practice in the Los Angeles area. Saneto reported on 47 patients seen at Seattle Children's Hospital. Sulak, who is based in Maine, contributed four detailed case studies. They aggregated their results:

"Of 272 combined patients from Washington State and California, 37 (14%) found cannabis ineffective at reducing seizures, 29 (15%) experienced a 1–25% reduction in seizures, 60 (18%) experienced a 26–50% reduction in seizures, 45 (17%) experienced a 51–75% reduction in seizures, 75 (28%) experienced a 76–99% reduction in seizures, and 26 (10%) experienced a complete clinical response.

Overall, adverse effects were mild and infrequent, and beneficial side effects such as increased alertness were reported. The majority of patients used cannabidiol (CBD)-enriched artisanal formulas, some with the addition of delta-9-tetrahydrocannabinol (THC) and tetrahydrocannabinolic acid (THCA)."

Most newsworthy —historic, actually— is the fact that a peer-reviewed publication has acknowledged the validity of data compiled by cannabis clinicians. Goldstein and Sulak are each identified as running "a private cannabinoid medicine practice." Kudos to the editors at *Epilepsy & Behavior* who recognized their findings as worthy of inclusion in their journal! A wall has been breached —kind of like when the Baseball Hall of Fame enshrined the star players from the Negro Leagues at Cooperstown. Sulak, Saneto and Goldstein are our Satchell Paige, Buck Shaw and Josh Gibson.

*A peer-reviewed publication acknowledges the validity of data compiled by cannabis clinicians*

From now on, when medical-establishment experts review the evidence on cannabis as a treatment for epilepsy, the paper by Sulak et al cannot be overlooked. It's part of "the literature." It has been "published."

Because Sulak, Goldstein, and Saneto are cannabinoid-medicine specialists who care for patients in ways that go beyond documenting seizure reduction, their paper provides extremely pertinent information not typically found in medical journals. Consider the following dense, poignant paragraph listing the "non-medical risks" that physicians must bear in mind when recommending a trial of cannabis to the parents of epileptic children:

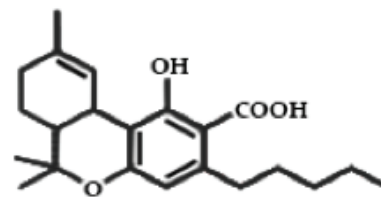
"Availability of a consistent supply of the medication is frequently interrupted due to horticultural, manufacturing, and economic factors. Current market prices for artisanal cannabis preparations observed in Maine, California, and online range from 5 to 50 cents per milligram. Higher dosing ranges are financially unfeasible for many patients unless they grow and produce their own medicine, a complex process that presents

many potential interruptions in treatment. Sudden loss of access to cannabinoids may result in rebound seizures. Hospital admissions present challenges, and patients or their guardians often must choose between interrupting cannabis treatment and violating hospital policies that forbid self-administration of medications, especially those with Schedule I status.

In one of the sites, the hospital has families sign a waiver and allows them to administer home dosing of product, but does not provide storage. The potential for disruption of medical treatment or family structure related to child protective services and other legal agencies, even when the patient and medical provider operate within state laws, must also be carefully considered on a case-by-case basis."

The bottom line from Sulak et al: "Overall, the safety profile of quality-controlled herbal cannabis preparations is likely equal or superior to most Anti-Epileptic Drugs... Herbal cannabis has remarkably low toxicity, even at high doses, and no lethal dose of cannabis has been described. Conversely, the morbidity of AEDs are the most common impediment to achieving full effective dosing due to multiple types of toxicity ranging from tiredness to memory problems and even death."

—O'S News Service



delta-9-tetrahydrocannabinol acid (THCA)

### Why THCA?

In "The Current Status of Artisanal Cannabis in the Treatment of Epilepsy in the United States," Dustin Sulak, DO summarizes a case involving a 10-year-old boy who was started on a THCA-rich extract. We asked why THCA instead of CBD?

Sulak replied that THCA is often easier to come by. Plus:

"When people respond to THCA they usually respond at a much lower dose than they do to CBD. As a result, the trial takes less time. When you start someone on low-dose CBD it can take several months to work them up to the effective dose. With THCA it seems to go much faster, and of course a lower dose is more affordable for the families. So in many cases I'm starting with THCA —especially when the problem only involves seizures. If there are cognitive or behavioral issues, pain, spasticity, or other symptoms, I start with CBD or THC.

Sulak et al acceptingly cite a paper reporting that a placebo effect influences the claim that cannabis reduces seizures. I have heard parents of epileptic children scoff —and have scoffed myself— at the notion of such a placebo effect. Sulak said it's probably real in some instances, a function of the parents' desperate hope for progress.

He added. "A mother told me this week her daughter's seizures were doing much better, down to three-four seizures per week. I looked at my notes from three months earlier and it was three to five seizures per week. While I believe that she may be doing much better in some global sense, and I have a tendency in general to believe my patients' statements as valid truth, if not a scientific finding, I don't think all reports of seizure improvement are always accurate."

### ECB blood serum levels

It was surprising to read in Russell Saneto's report on 47 patients from Washington State, "We are able to validate the product our patients are taking by serum analysis of drug levels."

Testing blood-serum cannabinoid levels is not being done by California doctors or patients. Sulak explained that Saneto had been involved in the clinical trial at Seattle Children's Hospital of Epidiolex, and that a lab in Pennsylvania had developed a panel to measure (certain) cannabinoid levels. Sulak hopes to get his patients access to a lab that can measure cannabinoid levels in the blood.

## The current status of artisanal cannabis for the treatment of epilepsy in the United States

Dustin Sulak <sup>a\*</sup>, Russell Saneto <sup>b</sup>, Bonni Goldstein <sup>c</sup>

<sup>a</sup> Integr8 Health, 170 US Rt. 1, Falmouth, ME 04105, United States  
<sup>b</sup> Seattle Children's Hospital/University of Washington, 4800 Sand Point Way NE, Seattle, WA 98105, United States  
<sup>c</sup> Canna-Centers, 15901 Hawthorne Blvd Suite #460, Lawndale, CA 90260, United States

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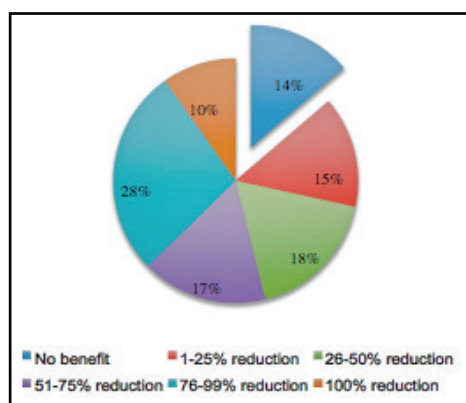
### ABSTRACT

The widespread patient use of artisanal cannabis preparations has preceded quality validation of cannabis use for epilepsy. Neurologists and cannabinoid specialists are increasingly in a position to monitor and guide the use of herbal cannabis in epilepsy patients. We report the retrospective data on efficacy and adverse effects of artisanal cannabis in Patients with medically refractory epilepsy with mixed etiologies in Washington State, California, and Maine. Clinical considerations, including potential risks and benefits, challenges related to artisanal preparations, and cannabinoid dosing, are discussed.  
**Results:** Of 272 combined patients from Washington State and California, 37 (14%) found cannabis ineffective at reducing seizures, 29 (15%) experienced a 1–25% reduction in seizures, 60 (18%) experienced a 26–50% reduction in seizures, 45 (17%) experienced a 51–75% reduction in seizures, 75 (28%) experienced a 76–99% reduction in seizures, and 26 (10%) experienced a complete clinical response. Overall, adverse effects were mild and infrequent, and beneficial side effects such as increased alertness were reported. The majority of patients used cannabidiol (CBD)-enriched artisanal formulas, some with the addition of delta-9-tetrahydrocannabinol (THC) and tetrahydrocannabinolic acid (THCA). Four case reports are included that illustrate clinical responses at doses <0.1 mg/kg/day, biphasic dose-response effects, the use of THCA for seizure prevention, the use of THC for seizure rescue, and the synergy of cannabinoids and terpenoids in artisanal preparations.

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**Table 1**  
 Percent seizure reduction attributed to the addition of artisanal cannabis; combined data from Washington and California.

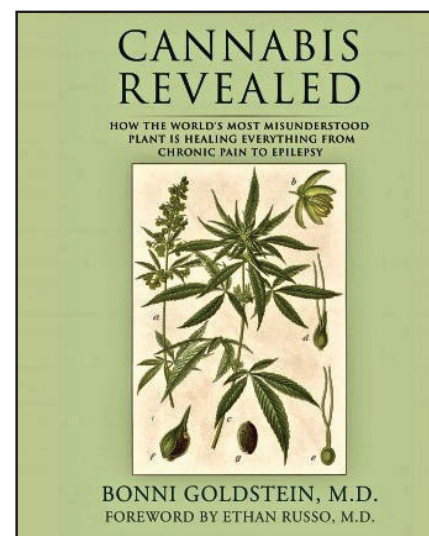
% Seizure reduction	California	Washington	Combined	Percent of total
0	27	10	37	14%
1–25	29	12	29	15%
26–50	25	23	60	18%
51–75	45	0	45	17%
76–99	75	0	75	28%
100	24	2	26	10%
<b>Total</b>	<b>225</b>	<b>47</b>	<b>272</b>	



### Three patients who benefited



DR. BONNI GOLDSTEIN WITH ARMAND (above), who has been seizure-free on cannabis oil since 2016. Center photo is with Izaiah, who has been seizure-free on cannabis oil since 2015 and has gotten off all pharmaceuticals. Photo at right is with Sean, who has had >99% seizure reduction on cannabis oil, and is off all pharmaceuticals. In her book, *Cannabis Revealed*, Goldstein wrote, "To my patients: I learn something new every day from you. I am honored to share your stories and your lives. I am in awe of the courage you show every day in your fight to feel well."



BONNI GOLDSTEIN is the Medical Director of Canna-Centers Wellness & Education. Within the center there is a 40-seat classroom offering seminars/webinars to anyone who wants to learn more about cannabis medicine. Details at [www.canna-centers.com](http://www.canna-centers.com).