



FDA Approves First Medicine Derived from Cannabis Plant



In a milestone decision, the Food and Drug Administration (FDA) has approved for the first time a medication derived from the cannabis plant. Epidiolex™, an oral solution of canna-World Health Organization Takes First Steps to Reschedule Cannabisbidol (CBD) developed by GW Pharmaceuticals in the UK, has been approved for the treatment of two rare seizure disorders, Dravet syndrome and Lennox-Gastaut syndrome. It is the first FDA-approved treatment for Dravet syndrome. Analysts predict Epidiolex™ will cost \$2,500 to \$5,000 per month.

Other cannabinoids produced synthetically in laboratories are currently available, but the FDA has previously blocked medicines derived from the cannabis plant. Marinol (dronabinol), a synthetic THC capsule, was approved by the FDA in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy.

Requests by pharmaceutical companies to produce generic versions from plant material have

been rebuffed by the FDA, even though it would lower the cost dramatically. Even generic dronabinol is about 10 times more expensive than comparable, commercially available cannabis-based products.

FDA approved medications can be prescribed by doctors, purchased in pharmacies, and typically covered by insurance. Patients who obtain medical cannabis through state programs must buy it from dispensaries or, if permitted, grow their own. Health insurance will not cover medical cannabis, though workers compensation insurance has in some cases.

While other clinical trials and pre-clinical studies of CBD confirm patient reports that it can be effective for a broad range of conditions, including other seizure disorders, Epidiolex™ has only been approved for the two rare pediatric seizure conditions.

Estimates of the incidence of Dravet syndrome range from 1 out of 15,700 to 1 out of 40,000 infants, while Lennox-Gastaut syndrome

accounts for just 1-4 percent of childhood epilepsy cases.

New Federal Bill Would Shield State Programs

A new bipartisan, bicameral federal bill was introduced in June that would empower states to determine their own cannabis policies. The Strengthening the Tenth Amendment Through Entrusting States Act (STATES Act) was introduced in the US Senate by Elizabeth Warren (D-MA) and Cory Gardner (R-CO) and in the House by David Joyce (R-OH) and Earl Blumenauer (D-OR).

If enacted, the STATES Act allows each state, the District of Columbia, Guam, and Puerto Rico, as well as several tribal governments, to develop cannabis access programs without interference from the Department of Justice or other federal agencies. While the bill would not legalize cannabis at the federal level, it would resolve many of the federal tax and banking issues that have hindered industry.

Oklahoma Voters Enact Robust Access Program

At the end of June, Oklahoma became the 30th state to enact a comprehensive medical cannabis program when voters approved State Question 788 by 56.8% to 43.2%.

Oklahoma Governor Mary Fallin made the decision to put the measure on the June primary ballot, when voters typically are older and more conservative than in the general election. The medical cannabis measure attracted almost 41,000 more total votes than all candidates for governor combined, indicating many voters turned out just to cast a ballot for safe access.

The initiative reflects a number of patient-focused principals from ASA's model legislation, including strong civil protections, reasonable possession amounts, and a right to personal cultivation. And it specifies no conditions, as all other states do.

Emergency rules governing the program will be considered by the Board of Health July 10. Application information will be available July 26 for all the defined categories, and applications will be accepted no later than August 25.

WHO Takes First Steps to Reschedule Cannabis



World Health Organization

In June, Americans for Safe Access and other members of the International Medical Cannabis Patients Coalition (IMCPC) testified at the 40th meeting of the World Health Organization's (WHO) Expert Committee on Drug Dependence (ECDD) in Geneva, Switzerland.

The ECDD is assessing the international classification of cannabis in light of its medical uses and potential harms. Members of ASA and IMCPC produced and delivered four reports with references and recommendations on the cannabis plant and cannabis resin, extracts and tinctures of cannabis, cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC).

International bodies have been calling on the WHO to address the scheduling of cannabis for almost a decade. In 2009, the Commission on Narcotic Drugs requested an updated review by ECDD. In 2013, the International Narcotics Control Board asked WHO to evaluate "the potential medical utility of cannabis and the extent to which cannabis poses dangers to human health." Cannabis is currently scheduled in Schedules I and IV of the Single Convention on Narcotic Drugs as amended by the 1972 Protocol (the "Single Convention").



"The current international policies on cannabis are based on a League of Nations report from 1935," said Sherer. "They are having a detrimental impact on patients worldwide and do not reflect the reality of over 30 countries globally that have passed medical cannabis laws."

Advocates filed a Critical Review and three Pre-Review in response to the ECDD technical documents, which outline the medical efficacy, toxicology, and epidemiology of various preparations of cannabis.

Patient advocacy groups at the meeting from Argentina, Mexico, Uruguay, France, Germany, New Zealand, the Netherlands, South Africa, and the United States all recommended changes in the international scheduling of cannabis and medical products made from it.

ASA 2018 COURAGE AWARD: Mark and Christy Zartler, Texas

For Christy Zartler, the breaking point came four years ago when her 14-year-old daughter's neurologist announced that he'd exhausted all the pharmaceutical treatments available. For ten years, Christy and her husband Mark had been struggling to control Kara's severe autism with conventional medications, but all the benzodiazepines and antipsychotic medications the doctors had tried had failed to stop her self-injuring behaviors. She was rendered near catatonic by the medications but still hit herself in the face as many as 3,000 times each day, at times breaking bones and inflicting injuries on anyone who tried to restrain her.

Yet Christy and Mark knew there was an alternative that did work for Kara. It was just illegal in their state of Texas. So off Christy went to Austin to lobby lawmakers for a medical cannabis law.



Four years before, thanks to the intervention of a neighbor who offered a medicated cookie, they had discovered that cannabis could stop Kara's self-injuring behaviors. Since then, they had been quietly using it as an intervention when her fits grew bad. Now, with Kara's neurologist admitting defeat, they had decided it was time to more fully integrate cannabis into her care. And it was time to change the law in Texas.

Trip after trip to Austin to talk to lawmakers took time and money, but the Zartlers were determined to make a difference for their

family and others like them. If anyone asked Christy, who is a nurse practitioner, if they were giving Kara cannabis, she told the truth. They were, and it worked 100% of the time.

The same was true in their community. Kara does not speak but goes to school, and her teacher and the school nurse noticed big changes in her as soon as the cannabis treatment started and asked what had changed. The Zartlers told them, just as they shared their decisions with Kara's pediatrician, neurologist, and physical therapist. Each of these professionals was under legal obligation to report the Zartlers to the authorities, but none did.

"Kara's condition is so severe, and the benefits are so dramatic, no one really questions what we're doing," says Christy.

Then in February 2017, with a promising medical cannabis bill pending in the state Senate, Mark went very public. He videotaped one of Kara's self-hitting fits and his intervention: a cannabis vapor-filled bag administered through a medical mask. In the video he posted to his facebook page, almost immediately Kara stops hurting herself and visibly relaxes. Within hours it went viral. A local news station saw it and contacted them to do a story, then two more and the *Dallas Morning News*. After seeing the video, a representative from south Texas immediately introduced in the House a companion bill to one pending in the Senate.

Then came the knock from Child Protective Services. Under Texas law, giving an illegal drug to a minor is classified as child abuse, and CPS had reason to believe Mark was abusing his daughter. Ultimately, the investigation was resolved, perhaps largely, Christy says, because

Kara's case is so challenging CPS didn't want to take responsibility for the risks of caring her.

Kara turned 18 last November, and this March, the Zartlers had to go to court for a guardianship hearing. They knew the cannabis therapy would be an issue, so they reached out to the reporter for the *Dallas Morning News* who had written about Kara before. Her article about the hearing dominated the front page.



In May, the Zartlers traveled to Washington, D.C. for ASA's National Unity Conference and Lobby Day meetings they had scheduled with their Congressional representatives, including Rep. Pete Sessions. Christy had called to reconfirm twice that they'd be meeting in person. But when they arrived at his office, he was not there. Christy posted a message of disappointment online and went on to the next meeting.

Within minutes, the phones in Rep. Session's office were ringing with the first of what would be hundreds of phone calls from concerned citizens. The Saturday morning after their return home to Dallas, Christy Zartler answered the phone to discover Rep. Sessions personally calling to arrange a meeting.

The Zartlers recognize the power of public advocacy and are courageously sharing their family's story with the world, despite the lack of legal protections in Texas. They understand the risk, but by being public, they have also been able to attract support and share it.

The family's videos on facebook and youtube have reached an even wider audience, with hundreds of millions of viewers who have seen for themselves what this plant can do for desperate cases such as Kara's.

"The religious community has been wonderful," says Christy. "They see the plant as something God put on earth to help Kara."

Now that Kara is using cannabis consistently, she has weaned off most other medications and has had profound cognitive improvements.

"Cannabis can make miracles," Christy says.

ACTION ALERT: Urge Congress to Pass the STATES Act!

Contact your Congressional representatives today to urge them to support new legislation in the House and Senate to resolve the medical cannabis conflict. The STATES Act (S. 3032/H.R.6043) would put cannabis policy where it belongs, with the individual states rather than with the federal government. The STATES Act does not make medical cannabis legal federally but allows states to set policies for patients without federal interference. Take action today at safeaccessnow.org/pass_the_states_act.

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