ASA Testifies at FDA Hearing on Regulating CBD

The U.S. Food and Drug Administration (FDA) on May 31 held a nearly 10-hour public hearing to collect scientific information and data on cannabis and cannabis-derived products, including cannabidiol (CBD). Americans for Safe Access’s Director of Patient Focused Certification (PFC), Heather Despres, was among those selected to present. Her testimony can be seen on ASA’s YouTube channel.

As part of the ASA and PFC mission to ensure access to safe products, Despres told FDA officials about safe production and how standardization of the industry across all states will improve patient access and provide consistent products to patients across the country.

The questions posed by the FDA include questions around manufacturing and product safety, industry standards, and labeling. The PFC program was created around these very issues, so Despres was able to advise the FDA on current industry standards that can be adapted on a national level to encourage consistency in products between states.

The FDA received almost 400 requests to present and/or provide oral remarks at the hearing. Americans for Safe Access was one of 113 organizations selected to give a formal presentation, and one of only 72 organizations selected to give a full presentation with slides.

Several organizations argued that the FDA should allow the sale of hemp-derived CBD-infused under the 2018 Farm Bill. Some also suggested that these products be regulated under the existing dietary supplement framework.

Patient advocates urged additional scientific research on the therapeutic value of CBD in treating conditions such as epilepsy, Alzheimer’s and dementia. Many Americans have already turned to CBD products to assist with general wellness.

A critical review by the World Health Organization determined last year that CBD’s safety profile and lack of abuse potential means it does not need to be a controlled substance. The FDA classifies CBD as a controlled substance but does not currently allow the sale and marketing of CBD-infused products because a CBD medicine, Epidiolex, has been approved by the agency as a Schedule V drug.

The FDA commissioner said in April that regulations may be released as early as this summer. The FDA is taking written public comments until July 2. See this month’s Action Alert for how to submit comments.

Colorado Now Allows Doctors to Substitute Cannabis for Opioids

Colorado Governor Jared Polis has signed into law SB-013, a bill that allows Colorado physicians to authorize individuals to use medical cannabis instead of opioids, including for acute pain. The bill also removes specific specialist physician requirements for patients who are minors and allows them to consume non-smokable forms of cannabis on school grounds. The law goes into effect August 2.

A majority of states allow medical cannabis to be used for chronic pain, but only a handful allow its use for acute pain or other conditions for which an opioid may be prescribed.

“ASA applauds Governor Polis for signing SB-013 and state lawmakers for doing their part to reduce opioid overdose deaths by allowing the substitution of cannabis for opioids in pain management,” said David Mongone, ASA’s Director of Government Affairs. “ASA launched a national campaign End Pain, Not Lives in 2017 to promote cannabis as a tool to combat the opioid crisis, and we’re gratified to see another state adopt this approach.”

Americans for Safe Access provided testimony in support of this bill in January.

Colorado joins Illinois and New York in allowing cannabis to be substituted for opioids.
In 2011, ten years after enlisting in the U.S. Army and serving tours of duty in Egypt and Afghanistan, Todd Larkin was discharged an E5 Sergeant and returned to his wife and kids in his hometown of Ardmore, Oklahoma. He had joined the military straight out of high school, and returned to work and coach at that school, but within a year, the Veterans Administration diagnosed him with post-traumatic stress disorder and depression. His mental health deteriorated over the next few years until his mood problems got him suspended from coaching football for a couple of games and he became suicidal.

“I was going down a road that wasn’t me,” he says. That’s when a friend from high school intervened, telling him repeatedly that he needed to try cannabis. “I didn’t think it would do anything,” Todd says. “My wife was pretty adamant about me not trying it.”

But Todd began to do research and reached out to people in the cannabis industry with questions. He became convinced it was worth a try, and broached the idea with his wife again. They decided to do a short trial using cannabis obtained on the illicit market, as there was not legal access in Oklahoma yet.

“After about a month, we were completely sold,” Todd says. “We both saw a complete change in my mentality and mood. It was night and day from the VA meds.” Todd was being prescribed nine separate medications, including Xanax, Prozac, a sleeping medicine and two more drugs to control the stomach problems from the other medications. To identify and obtain the types of cannabis medicine that work for him, Todd and his wife made trips to neighboring Colorado.

In 2017, sitting at dinner one night, Todd told his wife she should prepare herself, because he was ready to share more of his story. She was ready for it because she’d seen how much it helped not just his life but hers and the family’s.

Todd resigned from the high school to work full time on providing safe access to veterans and other patients in need in Oklahoma. He and his wife went to Las Vegas to meet with friends in the industry, tour facilities and meet manufacturers. When they came home, Todd was putting gas in his car when he discovered CBD being sold in his local gas station.

“I was disheartened by how it was being sold and what people were being told,” he says. He decided he needed to get involved to help ensure quality products and educate consumers and other veterans.

In January 2018, Todd opened Pure Wellness Medical providing CBD products. He was also involved in the campaign that got State Question 788 on the June primary ballot. June was also the month he formed Texoma Veterans Alliance, a cannabis-specific group that now has over 100 members, with 70 or so participating at meetings that include education on topics such as safety and cultivation.

After the state’s voters approved one of the most robust medical cannabis programs in the nation, they became a full-fledged medical cannabis dispensary in October 2018, now seeing as many as 200 or more patients a day. In support of his patients who are veterans, Todd reaches out to local businesses such as a plumbing company for donations to cover the cost of medicine. As a result, he was able to outfit 58 veterans with WarFighter CBD last month. Like him, many were being treated by the VA but not seeing good results.

Todd’s outreach includes lobbying at the state capitol and in Washington, D.C. The took a group of veterans to the state house in February to testify before lawmakers about program changes, pushing for, among other things, a reduced-price registration for veterans. Originally set at $500 per patient, the governor just signed a bill to reduce it to $22 for veterans, starting November 1. Oklahomans on fixed incomes will be eligible for the same reduced-cost registration.

This Memorial Day, Todd went to D.C. for a rally with the veterans’ group Plants Over Pills across from the White House.

“It was the second time I’d ever told my story. It was very refreshing,” Todd says of speaking at the rally of about 80 veterans. “Listening to other vets reminded me I’m not alone.”

Borrowing from what he learned attending ASA’s Lobby Day in March, he organized lobbying visits for the veterans, getting 40 veterans into 12 different meetings with national lawmakers or their staff.

Todd’s end goal is federal medicinal legalization, but he’s also focused on ensuring that Oklahoma has a good program. The state will not allow medicinal cannabis to be given away, but Todd’s working on establishing a program similar to one in Oregon that allows for “waste” or “expired” medical cannabis to be donated to veterans.