

July 2, 2019

Norman Sharpless, Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

**RE: Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds;
Public Hearing; Request for Comments**

Dear Commissioner Sharpless,

United Spinal appreciates the opportunity to provide comments on the Public Hearing for Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds.

United Spinal Association is the largest non-profit organization, founded by paralyzed veterans, dedicated to enhancing the quality of life of all people living with spinal cord injuries and disorders (SCI/D), including veterans, and providing support and information to loved ones, care providers and professionals. United Spinal has over 70 years of experience educating and empowering approximately 2.5 million individuals with SCI/D to achieve and maintain the highest levels of independence, health and personal fulfillment. United Spinal has over 50,000 members, 54 chapters, close to 200 support groups and more than 100 rehabilitation facilities and hospital partners nationwide including 10 distinguished Spinal Cord Injury Model System Centers that support innovative projects and research in the field of SCI. United Spinal Association is also a VA-accredited veterans service organization (VSO) serving veterans with disabilities of all kinds.

Currently, 33 states and Washington, DC, allow medical use of marijuana under State law and 14 additional States have State law medical programs that are limited to CBD products. In addition, 10 states and Washington, DC, have legalized marijuana for recreational use under State law, and 13 additional States have decriminalized recreational marijuana possession under State law in some form. Because of these state actions, the previous administration issued guidance to support these actions. These rules were rescinded in 2018 which has since created a patchwork of legal uncertainty. As more states move forward with medical and recreational marijuana legalization, it is critical that Congress take action to protect their right to do so.

For this reason, United Spinal supports the passage of the Strengthening the Tenth Amendment Through Entrusting States (STATES) Act, which ensures that each state has the right to determine for itself the best approach to marijuana within its borders. This bill extends these protections to Washington, DC, U.S. territories and contains common-sense guidance to ensure states are regulating in a rational and safe manner. We also support H.R. 712/S.179 The VA Medicinal Cannabis Research Act of 2019 which direct the Secretary of Veterans Affairs to carry out a clinical trial of the effects of cannabis on certain health outcomes of adults with chronic pain and post-traumatic stress disorder. We also support H.R. 601, The Medical Cannabis Research Act which increases the number of manufacturers registered under the Controlled Substances Act to manufacture cannabis for legitimate research purposes and authorizes health care providers of the Department of Veterans Affairs to provide recommendations to veterans regarding participation in federally approved cannabis clinical trials.

According to, *Advances in Experimental Medicine and Biology*, in 'Chronic Pain Following Spinal Cord Injury'¹ as many as 60-80% individuals with spinal cord injury (SCI) experience pain, with at least one third reporting severe pain. For many United Spinal members, neuropathic pain is an ongoing, daily experience. People with SCI tend to experience neuropathic pain at or below the damaged areas of their spinal cords. Diabetics with severe neuropathy mostly feel it in their lower extremities. The pain is always related to damaged nerves and is a symptom of electrochemical nerve impulses being misdirected, amplified, or electrified. No single painkiller seems to erase it entirely, but there are ways to dampen or dull it —to quiet the constant white noise of pain. Providing effective therapy for this pain can be tricky. In 2013, Valerie Bohrman, 28 of Hood River, Oregon sustained an incomplete spinal cord injury in a car accident. Bohrman knows about pain, both professionally and personally. She was three months from completing her residency as a nurse anesthetist in 2013 when she sustained a C5 incomplete spinal cord injury in a rollover car accident. Her mother, also a nurse anesthetist, made certain that Valerie was well-medicated for pain during her first two weeks in ICU. But when she emerged into the "real world," she experienced the full effect of neuropathic pain for the first time.

"The pain is absolutely maddening," she says. "I can understand how people can go crazy with it. From my shoulders down it felt like thousands of bugs with hot poker on their legs, marching under my skin. For the most part, my whole body felt this, but different in each area. But it's worse in my hands, feet, calves, and abdomen." Since her SCI is incomplete, her neuropathic pain attacks a number of areas below her injury level.

Bohrman routinely takes a very high dose — 4,500 mg/day, three doses of 1,500 mg — of Neurontin (generic name: gabapentin), an antiepileptic medication that is often prescribed for neuropathic pain. She also takes Cymbalta (generic name: duloxetine), an antidepressant, and cannabis. According to a June 2015 study in *Pain and Therapy*, "Management of Neuropathic Pain Associated with Spinal Cord Injury,"² no single drug can eliminate neuropathic pain, but antiepileptic meds, antidepressants, opioids and cannabis are effective in dampening the pain.³

For Valerie and many others living with spinal cord injuries and chronic pain, medical marijuana, particularly those strains with a high CBD concentration, has dramatically improved their quality of life. This is why we advocate for rescheduling cannabis and lifting barriers to research. Thank you for your consideration. For more information, please do not hesitate to contact me at abennewith@unitedspinal.org or (718) 803-3782.



Alexandra Bennewith, MPA
Vice President, Government Relations

Cc: Lowell J. Schiller, Acting Associate Commissioner for Policy

¹ *Adv Exp Med Biol.* 2012; 760: 74–88.

<https://www.ncbi.nlm.nih.gov/entrez/eflink.fcgi?dbfrom=pubmed&retmode=ref&cmd=prlinks&id=23281514>

² Management of Neuropathic Pain Associated with Spinal Cord Injury, *Pain and Therapy*, June 2015: www.ncbi.nlm.nih.gov/pmc/articles/PMC4470971/#CR69

³ United Spinal's New Mobility Magazine, March 2017, <http://www.newmobility.com/2017/03/neuropathic-pain/>.
Additional Resources:

*Pharmacological Management of Neuropathic Pain Following Spinal Cord Injury, *CNS Drugs*, 2008: www.ncbi.nlm.nih.gov/pubmed/18484790

*Living a Healthy Life With Chronic Pain, Bell Publishing Co., Boulder, Colorado: 2015; also available at Amazon.com.