



ASA Analysis Reveals Flaws in DEA Rescheduling Denial



The Drug Enforcement Administration (DEA) relied on flawed or outdated scientific research when it rejected petitions to reclassify cannabis as having medical use, an analysis by Americans for Safe Access revealed this month. The new ASA report contrasts the research the DEA used with the full body of available data, including the research ASA used in its independent, peer-reviewed 8-Factor Analysis, which mirrors the analysis the Department of Health and Human Services (HHS) was required to provide. All members of Congress have been sent the report, titled "DEA's Denial of Existing Medical Cannabis Research: A Peer-Reviewed Comparative Analysis of DEA's 'Denial of Petition to Initiate Proceedings to Reschedule Marijuana.'"

On August 10, the DEA denied two petitions to move marijuana from the Schedule I classification it was assigned in the Controlled Substances Act of 1970 (CSA). The DEA denial claims cannabis has no accepted medical use in the United States, has a high potential for abuse, and lacks an acceptable level of safety



for use even under medical supervision. Those flawed findings are based on a scientific and medical evaluation and scheduling recommendation provided by HHS, including the required 8-Factor Analysis.

"Our analysis shows that the DEA failed to take into account over 9,000 patient-years of placebo-controlled clinical research with standardized cannabis-based medicines," said ASA Chief Scientist Dr. Jahan Marcu. "Instead, nearly one third of the data cited in their report was derived from survey-based research, much of which does not have clinical significance, and almost 40% of the agency's report relies on outdated research articles."

While the DEA failed to conclude cannabis should be moved from Schedule I, their analysis marked a step forward from previous rescheduling decisions. The DEA now acknowledges cannabis satisfies several of the factors in the HHS's 8-Factor Analysis. There is no significant diversion of the substance from legitimate channels (Factor 1b). Cannabis is related

to other approved drugs with acceptable safety profiles (Factor 1d). There is no evidence for long term harms associated from the chronic use of cannabis (Factors 2 & 3). The gateway hypothesis is not supported by scientific evidence (Factor 6). And cannabis is not a precursor to another controlled substance (Factor 8).

"It is clear that the administrative process for rescheduling cannabis is broken and unworkable," said ASA Executive Director Steph Sherer. "It is up to Congress to rectify this situation by passing the CARERS Act."

PFC Educating Stakeholders, Developing New Standards

Staff from ASA's Patient Focused Certification (PFC) program have been traveling the globe educating stakeholders about regulatory developments, while working to create new accreditation standards for laboratories testing cannabis products.



PFC staff have just completed a multi-city tour of California to educate participants on current trends in regulations. The tour was focused on demystifying the implementation of the state's Medical Marijuana Regulation and Safety Act being carried out by a new Bureau of Medical Cannabis Regulation. The educational tour spanned 11 cities from one end of the state to the other.

PFC has also begun work with A2LA, the largest accreditation body in the U.S., on international standards for cannabis testing laboratories. PFC and A2LA are creating an ISO17025-type accreditation for cannabis that will incorporate regulatory compliance into the scope of accreditation.



So far this year, PFC has completed inspections and assessments of dispensing, manufacturing, cultivation, and laboratory operations in both the U.S. and internationally, including a laboratory in the Czech Republic that has begun testing CBD and other cannabis products available in Europe.

PFC's international program is also conducting research on laboratory methods. As part of the program, the terpene and cannabinoid pro-

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Ohio Medical Cannabis Law Takes Effect



Ohio's medical cannabis law went into effect last month, though implementation of the new law may take another two years. Medical cannabis use is now legal for qualifying patients with certain conditions, such as pain, cancer, AIDS and PTSD, but there is no legal means to obtain it, and physicians do not yet have guidance from the state medical board on issuing recommendation.

Eventually, dispensaries will be licensed by the state Board of Pharmacy, which is currently developing licensing rules. State law prohibits smoking cannabis, but vaporizing, oils, tinctures, edibles and topicals will be allowed for patients qualifying under a broad list of medical conditions. The state Medical Marijuana Advisory Committee is slated to have members appointed by early October.

Appeals Court Says Patients Can't Buy Guns



A federal appeals court last month ruled that state-registered patients are barred from purchasing firearms because cannabis use is likely to produce "irrational or unpredictable behavior" that makes them dangerous. The case was brought by a Nevada woman who was not allowed to buy a gun because the store owner identified her as a medical cannabis cardholder.

In 2011 the Bureau of Alcohol, Tobacco and Firearms issued a letter to gun sellers that federal law that prohibits gun purchases by an

"unlawful user and/or an addict of any controlled substance" applies to patients in state medical cannabis programs. The ruling by the U.S. Circuit Court of Appeals for the 9th Circuit hinged on earlier cases that found those who committed violent crime were more likely to be a drug addict or have a history of using illegal drugs other than marijuana.

Researchers have noted that cigarette smoking also correlates to criminal behavior, and alcohol use has a far stronger association with violent crime than cannabis use.

ASA Activist Profile: Dixie Pace Family, South Carolina

Dixie Pace's seizures started at age seven. At first, it was one every other week or so. After a year, they were weekly. With each passing year, the frequency increased until, a decade later, she was experiencing 50-100 seizures a day. By then, she was taking or had tried every anti-seizure medicine available.

The sedative effects of those pharmaceuticals left her with a lisp so severe her mother had to translate for other family members, and the serious side effects included a deadly rash and psychosis. Grand mal seizures necessitated a helmet to protect her from head injuries, and drop seizures caused so many shoulder dislocations that arm braces were required. When a qEEG digital brain scan revealed that the medications she was taking were causing more brain damage than the seizures, her parents had reached the end.

"We had heard about cannabis," Dixie's mother April says, "We got to studying, and met two ladies who were advocates. We didn't think our kids would make it to Christmas."

This was in the Fall, two years ago. Dixie was 18. The three families tried to get CBD under South Carolina's new state law for pediatric seizure patients, but no one could find or obtain it. So they started looking for medicine on the underground market.

They started experimenting with CBD and THCa as much as they could, but like many patients in states without robust medical



Dixie and April in Maine

cannabis programs, they found it hard to obtain the types of medicine they sought, and often had to deal with shadowy, unreliable providers. In July, the Pace family took Dixie to Maine for three weeks. There, she was able to try several different cannabis strains and products, and her seizures dropped immediately to only five to seven a day. Her cognitive functioning improved dramatically, as did her ability to speak and be understood. Instead of 13 medications -- eight anti-seizure, four to treat the side effects, and a sleep medicine -- she now takes just two.

"We're living right now," says April. "Before we had nothing. There were phases when all we could do was lay on the couch. Then she was a zombie from the medications."

The Pace family has worked hard to educate elected officials in South Carolina. They have each of the past two years to expand South Carolina's highly limited medical cannabis protections to a robust program that provides safe access. Neither bill passed, but last session Sen. Davis started reading a patient story each day in the Senate. April reports a palpable change

swept over the statehouse. They will try again with a more limited bill in the next two-year session, which begins in January.

Dixie is 20 years old now, but after 13 years of attempting to manage her seizures, her mother is not done fighting for her and other kids who need medical cannabis.

Michigan Expands Access

MI Eight years after Michigan voters approved a medical cannabis initiative, state lawmakers have enacted a trio of bills to implement it by legalizing and regulating edibles and dispensaries. Michigan Governor Rick Snyder signed the bills on September 20, praising the expansion of safe access.

"This new law will help Michiganders of all ages and with varying medical conditions access safe products to relieve their suffering," Snyder said. "We can finally implement a solid framework that gives patients a safe source from which to purchase and utilize medical marijuana."

Montana Rolls Back Law

MT Thousands of patients in Montana lost access to medical cannabis last month as new restrictions eliminated dispensaries in the state. Five years ago, state legislators gutted the medical cannabis measure voters passed in 2004, and last month the court challenges ended.

Montana's more than 13,000 patients must either cultivate themselves or find a caregiver. Registered caregivers are now limited to providing for no more than three patients, but there were only 305 registered providers as of the end of July who indicated they will accept three. As a result, 12,000 registered patients no longer have a legal means of obtaining it as they need it.

Patient advocates have qualified a new initiative of the upcoming election that would reinstate much of the medical cannabis program. Montana state law allows the legislature to modify initiatives passed by voters.

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files resulting from different extraction methods such as ethanol, CO2 and water were investigated. Since then, PFC's Kristin Nevedal and Jahan Marcu have presented around the world on the program and its international research efforts.

ASA's PFC program has more verified professional trainings scheduled in the next few months. A training will be held in Sacramento, California Oct 17-21 and in Frederick, Maryland Nov 7-10.

ACTION ALERT: Help Renew Federal Protections!

The Rohrabacher-Farr amendment to the Department of Justice's (DOJ) budget has been helping defendants win in federal court by blocking injunctions and prosecutions. But it is set to expire at the end of September. Earlier this year, the Senate Appropriations Committee voted overwhelmingly to include it in next DOJ budget, but the House has yet to vote. You can help by sending an email to your representative thanking them for voting yes last year or encourage them to take another look if they voted against it.

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