Tab 1

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

SUZANNE SISLEY, M.D. ET AL., *Petitioners*, v. U.S. DRUG ENFORCEMENT ADMINISTRATION, ET AL., *Respondents*.	)	No. 20-71433

DECLARATION OF SUZANNE SISLEY, M.D.

1. I am the President and Founder of Scottsdale Research Institute, LLC ("SRI"). SRI is an Arizona based limited liability company and clinical trials site dedicated to advancing the state of medical care through rigorous research. It is located at 5436 E Tapekim Rd., Cave Creek, AZ 85331 and our website is at http://www.sriresearch.org/. SRI strives to conduct high quality, controlled scientific studies to ascertain the general medical safety and efficacy of cannabis products and examine forms of cannabis administration. SRI does not encourage recreational use of cannabis.

2. I am also a physician licensed to practice medicine in the State of Arizona and am in good standing. I completed my medical degree at the University of Arizona College of Medicine and did my residency at Good

Samaritan Regional Medical Center in the fields of Internal Medicine and Psychiatry. I also served as Clinical Faculty at St. Joseph's Hospital and Medical Center at the MercyCare Adult Medicine Clinic for indigent patients.

3. I have received many honors and awards for my work, both in private practice and in research. For example, in 2001, I won the UA's Leo B. Hart Humanitarian Award from the University of Arizona College of Medicine. I also received the Arizona Medical Association's highest honor, the President's Distinguished Service Award.

4. I have received significant support from patient rights organizations including veteran groups around the country, such as the American Legion. In September 2016, the American Legion passed a resolution in support of our research, urging the DEA to license privately-funded cannabis production to enable safe and efficient cannabis drug development.[1]

Private Practice

5. My private practice of Internal Medicine & Psychiatry has always had a focus on treating veterans as well as underserved populations across Arizona. I treat over 400 patients per month, averaging about 20 patients

[1] See https://archive.legion.org/bitstream/handle/20.500.12203/5763/2016N011.pdf. See also B. Bender, American Legion to Trump: Allow marijuana research for vets, Politico (May 20, 2017).

per day, primarily over telemedicine. The demographic breakdown of my practice is approximately 40% military veterans, 20% police and fire, and 40% patients enrolled with 8 different Native American tribes based in Arizona. My specialties include treating chronic pain, opioid dependence and PTSD.

6. My research interests are directly influenced by my experiences in private practice. More than a decade ago, I began noticing intractable PTSD and a suicide epidemic among veterans first-hand. PTSD is a mental health condition experienced by some who go through traumatic events. Symptoms vary from individual to individual. Common symptoms include anxiety, insomnia, depression, and nightmares. Currently there are limited approved pharmaceutical remedies for PTSD. Only two anti-depressants are approved by the FDA to treat PTSD.2

7. Many of my veteran clients with PTSD did not respond to conventional medications. Some clients told me that using cannabis helped alleviate their symptoms.3 For many, cannabis was the only drug that worked, reversing insomnia or easing depression and anxiety. Patients told

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2 See https://www.youtube.com/watch?v=Idujb84MwPE ("Weed 3") at 3:30 (April 19, 2015).

3 See Weed 3 at 5:00.

me that cannabis effectively quelled nightmares, flashbacks, and hypervigilance.

8. This first-hand experience inspired me to conduct clinical trials on the safety and efficacy of cannabis use to suppress treatment resistant PTSD, which I discussed in CNN's "Weed 3: The Marijuana Revolution,"[4] an April 19, 2015 special report by CNN's chief medical correspondent Dr. Sanjay Gupta.

The Road to Clinical Trials

9. I struggled for seven years to get approval from four different federal agencies to conduct clinical trials of cannabis as a treatment for PTSD symptoms in veterans.

10. In 2009, I began collaborating with the Multidisciplinary Association for Psychedelic Studies (MAPS) on a proposal for the FDA. On Nov. 11, 2010, MAPS' clinical research team submitted our protocol to the FDA, and FDA approval came in April 2011.

[4] Although the video does not appear to be available from CNN, the video is widely available online, for example on YouTube at https://www.youtube.com/watch?v=Idujb84MwPE. I am introduced in the video at 3:30, and our struggle to obtain all the necessary government permissions begins at 5:30.

11. On July 30, 2012, we submitted the protocol to the University of Arizona Institutional Review Board (IRB), which approved the study in October 2012.

12. Shortly after FDA approval, we sent the proposal to NIDA and PHS for approval. After a series of rejections, we finally obtained approval from these agencies around March 2014. That approval was critical because it allowed us to be able to purchase federally legal cannabis from NIDA, the only source of cannabis legal for use in federally regulated research.

13. On April 17, 2014, NIDA informed us that it did not have the cannabis we needed for our study. Shortly after that, NIDA told us that it would have to grow the cannabis we needed for our protocol.

14. In June 2014, I was released by the University of Arizona. They chose not to renew my contract of employment and two other subcontracts. My assistant professorship was terminated. Without an academic appointment, I was unable to continue my research with the university. I discussed this in an interview with CNN's Sanjay Gupta in July 2014.[5]

15. On November 2, 2015, we submitted our protocol to the DEA. As part of the approval process, the DEA inspected SRI. In April 2016, the DEA

[5] The interview is available at https://www.cnn.com/2014/07/12/health/marijuana-researcher-arizona/index.html.

approved my Schedule I license to do research with cannabis, which is still active. That license removed the last barrier to the study.

16. Our phase II clinical trials titled "Placebo-Controlled, Triple-Blind, Randomized Crossover Pilot Study of the Safety and Efficacy of Four Different Potencies of Smoked Marijuana in 76 Veterans with Chronic, Treatment-Resistant Posttraumatic Stress Disorder (PTSD)" began in early 2017, and we concluded it in early 2019. SRI treated 76 participants as part of the study. MAPS sponsored the study and it was funded with a $2.1 million grant from the Colorado Department of Public Health and Environment. The study's protocol is available online.[6]

NIDA Cannabis

17. On August 10, 2016, NIDA approved SRI's request to order 6.3kg of cannabis for our clinical trials. We had requested multiple cannabis strains with varying levels of THC and CBD, including high THC, high CBD, balanced THC/CBD, and placebo. On August 25, 2016, I received the first shipment. The cannabis arrived frozen, in dried bulk form. SRI tested the cannabis at a DEA-licensed laboratory.

[6] See https://www.sriresearch.org/MJP1-A6V1-FINAL-16MAR2017-Web%20(1).html.

18. The NIDA cannabis SRI received looked nothing like commercial grade medical cannabis one can buy from dispensaries states where medicinal cannabis is legal. NIDA cannabis consistently appears to have extraneous material like sticks, stems, and seeds. Many packages looked like the green powder shown below from a 2017 article on pbs.org that I am quoted in:[7]

19. I am also quoted in a 2017 Washington Post article titled "Government marijuana looks nothing like the real stuff. See for yourself," where a side by side comparison of commercial medicinal cannabis and NIDA cannabis can be seen:[8]

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[7] See C. Hellerman "Scientists say the government's only pot farm has moldy samples — and no federal testing standards," PBS (Mar. 8, 2017) (https://www.pbs.org/newshour/nation/scientists-say-governments-pot-farm-moldy-samples-no-guidelines). I took this picture.

[8] See C. Ingraham and T. Chappell, "Government marijuana looks nothing like the real stuff. See for yourself," Washington Post (Mar. 13, 2017) (https://www.washingtonpost.com/news/wonk/wp/2017/03/13/gov

20. In my opinion, both as a researcher and physician, the quality of this cannabis SRI had to use for its clinical trials had an adverse impact on the study results and sometimes on the study subjects. It is also my opinion that the poor quality of this cannabis would have an adverse impact on *any* safety and efficacy study.

21. For example, while conducting SRI's clinical trial, I noticed that bronchial irritation was a common complaint among the study subjects. I believe this side effect could have been mitigated if not eliminated had SRI been able to grow and use its own cannabis (which would have only contained the flowering tops of the plant without the extraneous plant material that can burn more harshly and cause excessive mucosal irritation) or simply if SRI could have used other cannabis that did not have extraneous material and excessively high levels of mold.

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ernment-marijuana-looks-nothing-like-the-real-stuff-see-for-yourself/?utm_term=.2dcae33401d3/).

22. Thus, NIDA cannabis was not only inadequate for the Phase II trial we just completed, but will be inadequate for further studies, such as Phase III clinical trials or other Phase II clinical trials. The presence of sticks, stems, and seeds and significant mold makes this drug unsuitable for clinical research in certain patient populations.

Application to DEA

23. On October 1, 2016, I submitted SRI's application for registration under the Controlled Substances Act. Shortly after, I submitted answers to a supplemental questionnaire.

24. Between the time I filed my application and August 2019, I followed up with the DEA numerous times. I believe I called DEA five times between June 2017 to August 2018. I called both DEA's local office in Arizona and DEA's national office. Each time I called to check in on the status of my application, I was told that nothing regarding my application status had changed.

25. DEA was always very polite but never offered any explanation for the delay. The local DEA office told me that they had no idea when the application would be processed.

26. In an August 30, 2018 e-mail, I wrote to DEA:

> I have contacted my local DEA office regularly asking them the status of our application over the past two years and continue to

> get a vague response saying they have no idea when the application will ever be processed.
>
> Can you provide us another update from the national office on when the applications will be evaluated?
>
> I know we've discussed this on the phone several times over the last few years and I continue to hear from you that you are unsure of when this application above will be assessed. So given the continual uncertainty from your office, I've stopped inquiring with national office because this seemed futile.

27. DEA's Unit Chief Regulatory Unit promptly responded to my August 30, 2018 e-mail. He stated: "The status of the application remains unchanged. The DEA and DOJ are discussing applications involving the bulk manufacture of drug code 7360 for research purposes."

28. DEA's inability to share details about SRI's application confused me. I have had nothing but positive experiences with DEA employees and have maintained good working relationships with local DEA staff. That continues to this day.

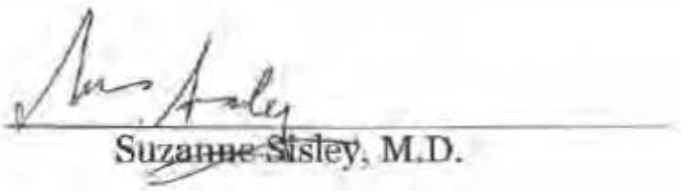
29. In Spring 2019, having still heard nothing from DEA substantively responding to my inquiries, I sought legal representation to assist me with the processing of my application. The recent NBCNews article entitled, "One doctor vs. the DEA: Inside the battle to study marijuana in

America," summarizes SRI's successful legal actions against DEA and the current research situation.[9]

30. As of the time of this declaration, SRI's 2016 application to cultivate marijuana to support its clinical research remains pending.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 24, July 2020.



Suzanne Sisley, M.D.

[9] https://www.nbcnews.com/news/us-news/one-doctor-vs-dea-inside-battle-study-marijuana-america-n1195436.