FULLSPECTRUMOMEGA
A Phytocannabinoids Life Science Corporation

Testimony before the United States House of Representatives Committee on the Judiciary

Subcommittee on Crime, Terrorism, and Homeland Security

Hearing on:

"Marijuana Laws in America: Racial Injustice and the Need for Reform"

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Statement (for the hearing record)

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Full Spectrum Omega, Inc.

Chairwoman Bass, Ranking Member Ratcliffe, and Members of the House Subcommittee on Crime, Terrorism, and Homeland Security. My name is Richard Brumfield, Founder and CEO, Full Spectrum Omega, Inc. (FSO). FSO is a privately held Service-Disabled Veteran-Owned Small Business (SDVOSB) phytocannabinoids company based in Los Angeles, CA focused on development of FDA approved phytocannabinoids to address unmet medical conditions while improving patients' lives.

I am a service disabled African American Veteran.

The Committee may be interested in learning that the company that manages FSO's unique structured molecular product line, MJRx, has been notified by the Medical Cannabis Safety Bureau/Department of Health that due to its high standards and excellent reviews its extraction company, La India Inc., has been chosen as a "state of the art" example of a California Manufacturing facility.

MJRx Corp. is an owner-executive management team with over 100 years combined legal cannabis experience and is comprised of 20 California professionals, managers, and cannabis operators that own and manage 13 city and 10 state MAUCRSA licenses since 2016.

MJRX provides professional services and resources, legal compliance, CCTT documentation, funding, start-up, personnel, training, education, operations and auditing.

For the past decade my company has developed a cannabis extract product line that has shown unique and remarkable positive results for a wide variety of medical conditions in patient use under California State Medical Cannabis provisions. FSO's products contain less than 0.3% (Δ9-THC) and are reported to be non-euphoric by patients. Results to date have generated significant interest and support for further development as U.S. Food and Drug Administration (FDA) approved products.

FSO currently has signed agreements with the Federal government to test its products as wound healing treatments secondary to burns and radiation as well as non-opioid analgesics for the treatment of pain. The government laboratories and

FSO are actively engaging with the Drug Enforcement Administration (DEA) to secure the required federal waiver to initiate the studies. As of to date, FSO's Federal partner has already received the necessary permit to conduct the studies. FSO's application is currently under review by the DEA.

The Committee should be aware that U.S. small biotech companies involved in cannabis R&D for drug development are struggling with the conflicted policies and convoluted processes that must be navigated in order to obtain the required schedule I registrations from the Drug Enforcement Administration (DEA).

Currently, U.S. provisions for access to cannabis plants and products are limited to a single source, the NIDA contracted farm at the University of Mississippi.

Stakeholders and we believe that term includes the FDA, understand the fundamental mismatch between the current single source model for both industry needs and the needs of academic research.

However, DEA Docket 447 with its focus on NIH grants and post-IND activities, as well as current proposed legislative language, does not clearly provide access to cannabis strains from sources sufficient to meet the requirements for all the research and development activities of product development by U.S. industry. Stakeholders understand that the intent of DEA Docket 447 and legislation is to provide expanded access to cannabis, but absent shared understanding of the differing needs of federal research institutions, academia and industry the path to effective solutions is still unclear. Rescheduling is a step in the clarification process, but it not the only step required.

I recently was asked to make a presentation to the Federal Food and Drug Administration hearing, "to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds" held in May 31 to talk about how the Federal government could help facilitate opportunities for cannabis businesses, and I would assume the majority of enterprises in this industry, like Full Spectrum Omega, are qualified small businesses.

I presented a series of issues, challenged and proposed solutions.

Issue: The FDA requested recommendations on data sources useful in providing safety and efficacy information.

Problem: The legal restriction to the type of product available from current sources (NIDA Mississippi Farm) does not allow for well-controlled studies of

medical cannabis products in use in State programs or developed by US industry, even if suitable for most academic research on cannabis and cannabis components.

Solution 1: Many States are establishing patient registries that either are or could be sources of fully documented Real World Data (RWD). FDA and Congress should work on ways to facilitate leveraging of this RWD for Real World Evidence (RWE).

Solution 2: FDA should work with DEA to facilitate approval of interstate transport of low THC products made under State program licenses for the purposes of research required for FDA approval without requiring DEA to approve the source (e.g., use hemp exclusion).

Issue: The new definition of hemp, when incorporated into the Controlled Substance Act (CSA), will not exempt from schedule I those products only made from plants that meet the % THC limit. The definition confers non-schedule I status to products containing no more than 0.3% THC as made from ANY type of cannabis. Hemp-derived is only a sub-class.

Problem: Lack of understanding of the 2018 Farm Bill definition of hemp. The new hemp definition applies to Cannabis Sativa plants, parts of Cannabis Sativa plants, products of Cannabis Sativa plants, etc. that meet the % limit as defined in the Farm Bill.

Solution: WHO (0.2%) and FDA (0.1%) have already made recommendations for products at low THC levels to be de- or re-scheduled. FDA needs to be proactive in working with the DEA on rescheduling actions to facilitate R&D supporting FDA approval of low THC products. Alignment with 0.3% THC hemp limit should be actively considered.

Issue: Product development research requires industry control of plant varieties and manufacturing processes. Most historic medical cannabis products are botanical blends of multiple components as determined by plant variety and extraction/manufacturing processes. Those are the majority of products already in use in State programs, with

demonstrated, but not fully documented, positive results. Such products are not available from NIDA Drug Supply Program.

Problem: Congressional supporters of medical research are embracing the position that medical products are best derived from generic cannabis/cannabis components supplied by a few bulk suppliers. There is a lack of understanding of industry requirements for product development activities vs. research activities and the viability of FDA approval under FDA drug development guidelines.

Solution: FDA should work to educate Congressional members and staff on the botanical drug approach and press Congress and DEA to provide access to industry developed products for the purposes of product development "research" activities leading to FDA approval.

Issue: The FDA doesn't want patients to forgo appropriate medical treatments by substituting unapproved products for approved medicines used to prevent, treat, mitigate or cure a particular diseases or conditions.

Problem: The timelines for approval are long and patients will continue to demand access to State program products. Significant amounts of epidemiological data are available on the safety and efficacy of cannabinoids, but additional data is being generated every day that is not available to the FDA.

Solution: While companies go through the FDA regulatory process, the FDA should use an expedited review process and consider making products available to, and data from, patients under the Right-to-Try and/or Expanded Access/Compassionate Use – i.e. FDA "Project Facilitate."

The FDA should work with industry to establish protocols, so as to make accommodations to utilize existing epidemiological data to reduce unnecessary study size and duration of clinical trials.

Issue: The FDA has pathways and guidelines that support seeking approval of cannabis-derived products but can't make access to US-made products legal. The DEA has provisions to make foreign made medical cannabis products legally available for medical R&D supporting FDA approval (import provisions), but no clear provisions for US industry made products.

Problem: The path to FDA approval of U.S. made cannabis-derived products are far more difficult than approval of foreign made products.

Solution: FDA and all federal agencies join in supporting a change to DEA policies and/or legislation that would fulfill their responsibilities to support US based companies as they seek FDA approval for cannabis-derived products.

As a small business I am concerned about the trends I see and implore the Small Business Administration to take steps to develop policies and guidelines that allow the growth of small entrepreneurs. The cannabis community is not afraid of hard work. Evolving the industry's ethos will take time, yes, but if done right, we may accomplish our goals and create a kinder and more compassionate society.

Finding our footing in this new era of big business may take longer, as stakes are high and competition is tough. But one thing is certain: 2019 will be a stellar year for the industry, especially for those who thrive on grit and grind.

Legalization process must be fair to everyone.

Legalizing marijuana must come with reinvestment in the communities most harmed by enforcement, with limitations on how police can interact with people who they suspect of a marijuana offense, with legal nonpublic spaces for smoking marijuana for those who cannot smoke in their residence, with a prohibition on deportation for people with marijuana convictions, and with full inclusion of those most impacted by criminalization of marijuana in the new marijuana industry.

While progress in reforming our nation's drug laws is vital, we must remember that if we legalize without righting the wrongs of past marijuana enforcement, we risk reinforcing the decades of disproportionate harm communities of color face and endure. People in the United States use and sell marijuana at roughly the same rate regardless of their race, yet a black person is almost four times more likely than a white person to be arrested for marijuana possession nationwide.

Having a marijuana conviction on your record can make it difficult to secure and maintain employment, housing, or secure government assistance for the rest of your life. This is why clearing people's records of marijuana convictions is a necessary addition to any legalization measure. If we believe that marijuana is not worthy of criminal intervention, then it is only right we stop the suffering inflicted on people by a marijuana prosecution. Especially since we know this disproportionately falls on the shoulders, and families, of low-income communities and communities of color.

Such efforts to extend racial justice must explicitly be tied to a program of economic justice.

Once again, I thank the Committee for allowing me to make my views and experience available to the hearing record. Full Spectrum Omega, Inc. intends to remain a viable SDVOSB and is looking forward to working with the Committee to assist in the development of appropriate legislative solutions.