October 4, 2022

The Honorable Chuck Schumer
Majority Leader
United States Senate
The Capitol, Room S-221
Washington, DC 20510

Dear Senate Majority Leader Schumer,

We write to inform you of our opposition to passage of H.R. 8454, the Medical Marijuana and Cannabidiol Research Expansion Act," and ask that it be kept off the Senate consent agenda for consideration by this Congress.

Like you, the undersigned organizations support broad research into the health, safety, consumption, and risks of cannabis use. These are important, critical areas of research that we agree deserve attention, which is why we cannot support the Act as written.

The Act does not expand research into existing cannabis medicines and only permits research for the purpose of a pharmaceutical New Drug Application (NDA) by large pharmaceutical companies.[1] Under current law, there are no barriers to research of cannabis and cannabis extracts for the purposes of an NDA aside from the controls that any pharmaceutical drug manufacturer must put on any Schedule I substance. Indeed, the FDA has approved Marinol and, more recently, Epidiolex, drugs that are THC and CBD, based on NDAs. It solves a problem that simply does not exist.

The Act fails to address the real issues. The barriers to research exist in obtaining existing market products for approval in *non*-drug pathways (such as dietary supplements, food additives, and other FDCA pathways); in obtaining existing products for health and safety testing across state lines to ensure consistency of products; in using human subjects in testing highways safety, motor skill, and other studies to determine more exactly intoxicating levels and effects.

These flaws cause the Act to have substantial and dire unintended consequences for the existing medical cannabis, industrial hemp, and dietary supplement industries.

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[1] *E.g.*, H.R. 8454, 117th Cong. (2d Sess., 2022) sec. 103, at p.14, ll. 1–5 ("The applicant will limit the transfer and sale of any marijuana manufactured under this subsection…for purposes of use in preclinical research or in a clinical investigation pursuant to an investigational new drug exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i))."); *id.* sec. 2, at p.4, ll.1–8; *id.* sec. 101, at pp.5–6, ll.24–25, 1–2; *id.* sec. 202 (only allowing commercial pharmaceutical drug manufacturer registration of products for production as drugs).

By disallowing existing product manufacturers from researching dietary supplement or other FDCA pathway use, Congress would only increase the ease of which the large pharmaceutical interests can file preclusive drug patents over existing products, akin to generics or dietary supplements, that are state-regulated and available nationwide.

Industrial hemp, dietary supplement, and medical cannabis manufacturers would be shut out of providing non-drug treatments derived from their respective versions of the cannabis plants due to conflicts with potential novel drug manufacturer patents. In the medical cannabis industry and patient access space alone, this outcome would result in the loss of approximately 400,000 jobs across the US, nearly $11.2 billion in state tax revenue, access to cheap and effective treatment for tens of millions of American patients.

It would further substantially undermine the regulatory, social equity, agricultural, labor, and small business regimes in each state that are set up to promote public health, safety, and minority entrepreneurship. Finally, the outcome would result in the diversion of pain management patients using medical cannabis back into opioid-based treatment and likely increase opioid-related mortalities.[2]

Additionally, Title III unnecessarily complicates and narrows the existing, longstanding interpretations of criminal law and doctor-patient relationships under the First Amendment and Controlled Substances Act, and potentially interferes with a 20-year-old nationwide injunction addressing the issue.[3] Doctors and medical professionals may currently discuss the benefits and risks of marijuana with their patients free from fear of criminal prosecution under the Controlled Substances Act, concurrent with the First Amendment. That discussion is governed by state medical practice law and tort, not the Controlled Substances Act.

Codifying the narrow view that Title III takes with respect to only "state-licensed Physicians" and professional speech opens the door to prosecution of large swaths of

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[2] *E.g.*, Nathan Chan et al., The Effects of Recreational Marijuana Legalization and Dispensing on Opioid Mortality, *Economic Inquiry*, Vol. 58, Issue 2, 2019, Page 589–606, https://doi.org/10.1111/ecin.12819; Amanda Reiman et al., Cannabis as a Substitute for Opioid-Based Pain Medication: Patient Self-Report. *Cannabis and Cannabinoid Research*. Dec 2017. 160–166. http://doi.org/10.1089/can.2017.0012; Philippe Lucas & Zach Walsh, Medical cannabis access, use, and substitution for prescription opioids and other substances: A survey of authorized medical cannabis patients, *International Journal of Drug Policy*, Vol. 42, 2017, Pages 30–35, ISSN 0955-3959, https://doi.org/10.1016/j.drugpo.2017.01.011.

[3] *Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002) (Schroeder, CJ.) (permanently enjoining the federal government from prosecuting state medical professionals under the Controlled Substances Act for providing patient advice regarding medical marijuana), *cert. denied.*; *see also National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2017) (Thomas, J.) ("Doctors and nurses might disagree about the ethics of assisted suicide or the benefits of medical marijuana…'[T]he best test of truth is the power of the thought to get itself accepted in the competition of the market,' and the people lose when the government is the one deciding which ideas should prevail.").

First Amendment-protected activity under an expansive, novel interpretation of the Controlled Substances Act's criminal reach (e.g., the statue is silent as to criminal liability and nurses, nurse practitioners, veterinarians, ophthalmologists, dentists, dental hygienists, pharmacists, and other medical professionals). Title III's scope should be concurrent with the nationwide injunction and practice in place for two decades, not less, and potential expanded criminal liability is of substantial concern.

Again, the undersigned support (and have supported versions of this bill which allow for) research into cannabis and its derivatives being used in all existing FDCA pathways. This bill simply does not allow that and would work to substantially harm cannabis research reform.

We thank you for your attention to these issues and leadership in the area of cannabis reform. Indeed, we would be remiss if we did not mention our support for your forward-thinking Cannabis Administration and Opportunity Act and our deep gratitude for your approach to reform and cannabis science. We look forward to working to advance broad cannabis research reform.

Sincerely,

Global Alliance for Cannabis Commerce (GACC)
Law Enforcement Action Partnership (LEAP)

Cc: The Honorable Mitch McConnell
Minority Leader
United States Senate
The Capitol, Room S-230
Washington, DC 20510