

ONE HUNDRED SIXTEENTH CONGRESS

**Congress of the United States****House of Representatives**

## COMMITTEE ON ENERGY AND COMMERCE

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December 16, 2019

The Honorable Frank Pallone, Jr.  
Chairman  
Committee on Energy and Commerce  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Anna G. Eshoo  
Chairwoman  
Subcommittee on Health  
Committee on Energy and Commerce  
202 Cannon House Office Building  
Washington, DC 20515

Dear Chairman Pallone and Chairwoman Eshoo,

We write to request that the Committee on Energy and Commerce hold a hearing to review legislative initiatives aimed at improving federally-sanctioned research on cannabis, such as H.R. 171, Legitimate Use of Medicinal Marijuana Act (LUMMA); H.R. 601, Medical Cannabis Research Act of 2019; and H.R.3797, Medical Marijuana Research Act of 2019. It is critical that the Committee review the current state of cannabis research and hear from the U.S. Drug Enforcement Administration (DEA), the U.S. Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA).

Cannabis is a Schedule I controlled substance under the Controlled Substances Act (CSA).<sup>1</sup> Research on these substances must be conducted in accordance with the CSA and requires a DEA-approved protocol to conduct research. If a researcher desires to increase the quantity of a controlled substance used for an approved research project, the researcher must submit a request to do so, which is then reviewed and must be approved by the DEA and the FDA.<sup>2</sup> Any other changes to the research from what is outlined in the approved protocol must also be reviewed and approved by the DEA.<sup>3</sup>

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<sup>1</sup> Comprehensive Drug Abuse Prevention and Control Act of 1970, P.L. 91-513 (Oct. 27, 1970).

<sup>2</sup> Research protocols, 21 C.F.R. 1301.18 (Mar. 9, 2010).

<sup>3</sup> *Id.*

The supply of research-grade cannabis is subject to the Single Convention on Narcotic Drugs,<sup>4</sup> which imposes certain obligations related to governmental oversight of its cultivation. NIDA has long acted as the agency responsible for overseeing the cultivation of cannabis for scientific research. For decades, the University of Mississippi's School of Pharmacy's National Center for Natural Products Research has had the sole contract with NIDA for the cultivation and procurement of research-grade cannabis.<sup>5</sup>

This single contract not only limits the supply, but also limits the diversity in quality, potency, chemical composition, and methods of consumption. Current research on the biological effects of cannabis might not replicate the experience of individuals using commercially available strains. Studies have found that cannabinoid levels in research-grade cannabis supplied by NIDA were not the same as those found in commercially available cannabis from state-legal dispensaries.<sup>6</sup> In fact, there is recent evidence that most of the commercially available cannabis was genetically distinct from the NIDA samples.<sup>7</sup> In 2016, the DEA announced it would allow additional growers to register in order to produce and distribute cannabis for research purposes.<sup>8</sup> Three years later, without any new approvals of additional manufacturers, the DEA announced in August that before making decisions on any pending applications, the agency would propose new regulations governing the growers program for scientific and medical research with a public comment period, which ended on October 28, 2019.<sup>9</sup>

Expanding the number of registered manufacturers is critical to understand fully the potential benefits and possible risks associated with cannabis use, as researchers must be able to study actual products that are currently used by consumers for both medical and recreational use. However, because of the current restrictions on quality, quantity, and use of cannabis in scientific studies, high quality research on both potential risks and benefits associated with cannabis has been challenging.<sup>10</sup> Given that cannabis is still classified as a Schedule I drug with "no currently accepted medical use and a high potential for abuse,"<sup>11</sup> rescheduling the substance

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<sup>4</sup> U.N. General Assembly, 1972 *Protocol Amending the Single Convention on Narcotic Drugs*, 1961 (Dec. 9, 1975), available at A/RES/3444, [http://www.unodc.org/pdf/convention\\_1961\\_en.pdf](http://www.unodc.org/pdf/convention_1961_en.pdf).

<sup>5</sup> National Institute on Drug Abuse, NIDA's Role in Providing Marijuana for Research (Aug. 27, 2019), available at <https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research>.

<sup>6</sup> Vergara, Daniela, L. Cinnamon Bidwell, Reggie Gaudino, Anthony Torres, Gary Du, Travis C. Ruthenburg, Kymron Decesare, Donald P. Land, Kent E. Hutchison, and Nolan C. Kane, *Compromised External Validity: Federally Produced Cannabis Does Not Reflect Legal Markets*, NATURE SCIENTIFIC REPORTS (Apr. 19, 2017), available at <https://doi.org/10.1038/srep46528>.

<sup>7</sup> Schwabe, Anna L., Connor J. Hansen, Richard M. Hyslop, and Mitchell E. McLaughlin, *Research Grade Marijuana Supplied by the National Institute on Drug Abuse Is Genetically Divergent from Commercially Available Cannabis*, BIORxIV (Mar. 28, 2019), available at <https://doi.org/10.1101/592725>.

<sup>8</sup> U.S. Department of Justice, Drug Enforcement Administration, *Applications To Become Registered Under the Controlled Substances To Manufacture Marijuana To Supply Researchers in the United States*, 81 F.R. 53846 (Aug. 12, 2016).

<sup>9</sup> U.S. Department of Justice, Drug Enforcement Administration, *Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of Marijuana*, 84 F.R. 44920 (Aug. 27, 2019).

<sup>10</sup> Taylor, Melissa, and Melissa Bailey, *Medical Marijuana's 'Catch-22': Limits On Research Hinder Patient Relief*, NPR (Apr. 7, 2018), available at <https://www.npr.org/sections/health-shots/2018/04/07/600209754/medical-marijuanas-catch-22-limits-on-research-hinders-patient-relief>.

<sup>11</sup> Schedules of Controlled Substances, P.L. 91-513 (Oct. 27, 1970).

would necessitate robust data on potential medical uses. Recent evaluations conducted separately by the FDA and the National Academies of Sciences, Engineering, and Medicine illustrate the challenge of meeting the required standard of evidence for demonstrating effective medical use and have concluded that lack of research was a significant factor in denying the rescheduling petitions in 2016.<sup>12</sup>

While the detrimental effects of chronic, heavy, recreational use of cannabis among individuals is relatively well studied, a number of areas are still not fully understood. For example, more study is needed to clarify the impacts on the brain, short- and long-term consequences of high potency products and novel modes of use, effects of cannabis use in older adults, and the safety and efficacy of existing products and those in development, ideally using clinical trial models.<sup>13</sup>

It is imperative that policy makers have scientific evidence to guide policy decisions. Regarding cannabis, policy decisions have outpaced the science. For example:

[S]tates that have legalized cannabis for adult use are doing so in an information vacuum, with less understanding of what it is and what it does than virtually any nutritional supplement currently on the market, and with far less information than they have on legal substances that are easily abused, such as alcohol or tobacco. Law enforcement officers don't even know at what point it is unsafe for marijuana users to drive.<sup>14</sup>

The urgency of addressing restrictions on cannabis research has been recently highlighted by recent legalization of one of its components, cannabidiol (CBD) derived from hemp. CBD is the second most prevalent of the active ingredients of cannabis and was removed from Schedule I if it is hemp-derived and produced in a manner consistent with the 2018 Farm Bill,<sup>15</sup> associated federal regulations, associated state regulations, and by a licensed grower. This substance is currently being marketed in a variety of products including drugs, food, dietary supplements, cosmetics, pet food, and other animal health products.<sup>16</sup> Although the FDA has approved one CBD-oral solution (Epidiolex) for the treatment of seizures associated with two rare and severe

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<sup>12</sup> U.S. Department of Justice, Drug Enforcement Administration, *Denial of Petition to Initiate Proceedings to Reschedule Marijuana*, 81 F.R. 53687-53766 and 53767-53845 (Aug. 12, 2016); National Academies of Sciences, Engineering, and Medicine, *The health effects of cannabis and cannabinoids: Current state of evidence and recommendations for research*, THE NATIONAL ACADEMIES PRESS (Jan. 12, 2017), available at <https://doi.org/10.17226/24625>.

<sup>13</sup> Sagar, Kelly A., and Staci A. Gruber, *Marijuana Matters: Reviewing the Impact of Marijuana on Cognition, Brain Structure and Function, & Exploring Policy Implications and Barriers to Research*, INTERNATIONAL REVIEW OF PSYCHIATRY (July 3, 2018), available at <https://doi.org/10.1080/09540261.2018.1460334>.

<sup>14</sup> Oweremohle, Sarah, *Why We Don't Know Much about Pot*, POLITICO (Oct. 14, 2019), available at <https://www.politico.com/agenda/story/2019/10/14/cannabis-medical-marijuana-research-000984>.

<sup>15</sup> Agriculture Improvement Act of 2018, P.L. 115-33 (Dec. 20, 2018).

<sup>16</sup> U.S. Food and Drug Administration, *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD* (July 7, 2019), available at <https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis>.

forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome,<sup>17</sup> it is illegal to market CBD as a food additive or dietary supplement. There is no evidentiary base for the vast health claims being made around CBD and other non-FDA-approved cannabis-derived products that are currently on the shelves for consumers, and there are legitimate concerns that these claims may lead consumers to forego appropriate medical care. Many consumers who try CBD products believe there is no risk; however, the limited data available suggests CBD use may pose serious health risks, including liver injury.<sup>18</sup>

Despite the accessibility of CBD on the market, research on this product remains challenging because of current law and cannabis's Schedule I status. Any cannabis-based research must use research-grade cannabis from the nation's sole provider of the product, The University of Mississippi's School of Pharmacy's National Center for Natural Products Research.<sup>19</sup> Uncertainty about the current legal landscape is further hindering research capabilities. Despite enactment of the Farm Bill and the legalization of CBD derived from hemp, regulatory authorities have not made clear what, if any, restrictions remain in place for researchers seeking to study these substances.

The current public health crisis of e-cigarette, or vaping, product use associated lung injury (EVALI) further underscores the urgent need to review the current state of cannabis research. More than 2,000 people, most of them using vaping devices containing tetrahydrocannabinol (THC), the principal psychoactive constituent of cannabis, have been diagnosed with e-cigarette, or vaping, product use associated lung injury (EVALI), resulting in nearly fifty deaths.<sup>20</sup> The Centers for Disease Control and Prevention (CDC) identified vitamin E acetate as a chemical of concern among people with EVALI. Vitamin E acetate can be used as an additive, most notably as a thickening or diluting agent in e-cigarette, or vaping, products that contain THC.<sup>21</sup> Those in the state-legalized cannabis industry have stated that vaping products now account for 30 percent or more of their business.<sup>22</sup> An analysis by The RAND Corporation found the fastest-growing segment of the state-legal cannabis market in Washington State was

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<sup>17</sup> U.S. Food and Drug Administration, FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy (June 25, 2018), *available at* <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms>.

<sup>18</sup> U.S. Food and Drug Administration, FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns (November 25, 2019), *available at* <https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details>.

<sup>19</sup> Hudak, John, *The Farm Bill, Hemp Legalization and the Status of CBD: An Explainer*, FIXGOV BLOG, Brookings Institution (Dec. 14, 2018), *available at* <https://www.brookings.edu/blog/fixgov/2018/12/14/the-farm-bill-hemp-and-cbd-explainer/>.

<sup>20</sup> Centers for Disease Control and Prevention, Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products (Nov. 19, 2019), *available at* [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information).

<sup>21</sup> *Id.*

<sup>22</sup> Richtel, Matt, *Marijuana and Vaping: Shadowy Past, Dangerous Present*, THE NEW YORK TIMES (Oct. 21, 2019), *available at* <https://www.nytimes.com/2019/10/21/health/marijuana-and-vaping-shadowy-past-dangerous-present.html>.

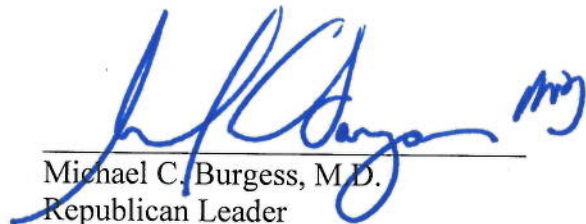
“extracts for inhalation,” which includes vape pens and cartridges,<sup>23</sup> yet the scientific community’s ability to research the use of THC in these products is limited.

We urge you to hold a legislative hearing regarding federally-sanctioned research on cannabis as soon as possible, with a panel of federal witnesses. This hearing would be an opportunity for members to learn about the aforementioned legislation that offers potential solutions to help improve the research landscape. Non-FDA-approved cannabis and cannabis-derived products are currently being used for the treatment of several medical conditions. In the absence of federally-sanctioned and scientifically-valid research on these products, all available evidence is generated in an uncontrolled study environment. The ability to study these products in clinical trial settings is necessary to assess the safety and effectiveness of these substances for the treatment of any disease or condition. Thank you for your consideration and we look forward to working with you to find solutions to cannabis research and all research on Schedule I substances.

Sincerely,



Greg Walden  
Republican Leader



Michael C. Burgess, M.D.  
Republican Leader  
Subcommittee on Health



Cathy McMorris Rodgers  
Member of Congress



H. Morgan Griffith  
Member of Congress

<sup>23</sup> Kilmer, Beau, Steven Davenport, Rosanna Smart, Jonathan P. Caulkins, and Gregory Midgette, *After the Grand Opening: Assessing Cannabis Supply and Demand in Washington State*, RAND CORPORATION (2019), available at [https://www.rand.org/pubs/research\\_reports/RR3138.html](https://www.rand.org/pubs/research_reports/RR3138.html).