

## *Cannabidiol and Marijuana Research Expansion Act*

### **To improve the process for conducting valid medical research on marihuana, and to streamline the development of safe and effective FDA-approved medicines.**

Marihuana and its compounds, in particular cannabidiol (CBD), show promise for treating a wide-range of diseases and disorders. However, there is a lack of research evaluating the potential medical benefits of marihuana because of barriers in federal law. As a result, many are using marihuana-derived products to treat serious illnesses that have not been approved by the Food and Drug Administration (FDA), and therefore have little information about their potential interactions with other medications, or the appropriate dose or delivery mechanism. Medical treatments should be based on sound science, and those who are sick deserve safe medications that have been proven effective.

That is why this bill would encourage valid scientific and clinical research on marihuana and its compounds, expand sources of research-grade marihuana, and promote the commercial production of FDA-approved drugs derived from CBD or other marihuana compounds.

#### **Bill Provisions:**

##### **Title I:** Reduces barriers to marihuana research by:

- Requiring researchers to be registered by the Attorney General if: (1) their research protocol is reviewed and allowed by the Secretary of Health and Human Services, the National Institutes of Health, or another federal agency; and (2) adequate security measures are in place to prevent abuse or diversion.
- Mandating that the Attorney General approve the complete application or request supplemental information within 60 days and must approve or deny the application within 30 days of receiving the supplemental information. If the application is denied, the Attorney General must provide written explanation.
- Expediting the process to request an increase in the quantity of Schedule I substances for approved research and changes in protocol. Those seeking to increase the quantity of drug being used would be required to notify the Drug Enforcement Administration (DEA), rather than DEA and FDA. This notification would be approved upon return receipt from DEA. Researchers seeking changes to their already-approved protocols that involve changes to the quantity, type, source, or conditions under which the drug is stored, tracked, or administered must notify DEA. Unless explicitly denied, the request is considered approved after 30 days. If DEA objects to a registrant changing his or her protocol due to insufficient security measures, the registrant has 30 days to appeal this decision. The bill explicitly maintains the Department of Health and Human Services' (HHS) authorities related to research protocols, including changes in the administration or dosing of the substances or the number of patients involved. It also requires the Attorney General to issue regulations related to these changes within 90 days.
- Requiring the Justice Department (DOJ) to approve or request supplemental information for applications to bulk manufacture marihuana for research that it has solicited in the Federal Register within 60 days, and requiring DOJ to consider the need for additional strains and specific manufacturing process in determining whether to approve these applications.
- Requiring marihuana to be stored in securely locked, substantially constructed cabinets – consistent with requirements for Schedule I and II drugs under DEA regulations – eliminating other more severe, cost-prohibitive measures as well as arbitrary enforcement.

- Amending the definition of marihuana in the Controlled Substances Act to exclude the synthetic equivalent of hemp-derived CBD that contains less than 0.3% THC.
- Requiring the Attorney General to determine if there is an adequate and uninterrupted supply of marihuana on an annual basis.
- Prohibiting HHS from reinstating the interdisciplinary review process for marihuana research.

**Title II:** Streamlines the development of FDA-approved drugs using CBD and marihuana by:

- Allowing accredited medical and osteopathic schools, practitioners, research institutions, and manufacturers with a Schedule I registration to manufacture marihuana for their research.
- Requiring DEA to license manufacturers for the commercial production of an FDA-approved CBD or marihuana drug.
- Allowing institutions appropriately registered with the DEA to import marihuana, marihuana seeds or CBD to conduct medical research for drug development.

**Title III:** Allows physicians to discuss the potential harms and benefits of marihuana derivatives, including CBD, as a treatment with the legal guardian of the patient if the patient is a child. It also allows physicians to discuss the potential harms and benefits of both marihuana and its derivatives with adult patients

**Title IV:** It requires HHS to report to Congress on the potential effects of marihuana, including its effects on the human body, the adolescent brain, and on cognitive abilities, such as those required to operate vehicles. It also requires HHS to report on the barriers to researching marihuana that is grown in states that have legalized its use, and to provide recommendations as to how to overcome these barriers. In addition, it encourages the federal government to facilitate more medical research on marihuana and its components, including the potential therapeutic effects on serious medical conditions.