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New Law Eases Federal Restrictions on Medical Marijuana Research and Cultivation

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The Medical Marijuana and Cannabidiol Research Expansion Act (MMCREA) became law last Friday. The bipartisan legislation will roll back federal restrictions on medical marijuana research and the cultivation of research-grade marijuana, as well as promote the development of US Food and Drug Administration (FDA)-approved drugs that use cannabidiol (CBD) and marijuana.

On December 2, President Joe Biden signed the MMCREA into law, after it had been approved by the US Senate two weeks prior and by the US House of Representatives in July. According to Senate Majority Leader Chuck Schumer, the legislation will “eliminate the red tape that hinders cannabis research, opening the door for new, innovative treatments derived from cannabis.”

MMCREA’s changes to the regulation of medical marijuana research include:

1. Streamlining the approval process of research applications submitted by practitioners;

2. Registering additional bulk manufacturers seeking to cultivate research-grade medical marijuana; and

3. Promoting the development of new drugs that use marijuana or CBD, including by allowing clinical trials through the FDA’s Investigational New Drug (IND) exemption program.

As the title implies, the MMCREA’s provisions apply to both marijuana and CBD. Under the Controlled Substances Act (CSA), marijuana refers to any part, resin, compounds, manufacture, salt, derivative, mixture, or preparation of a cannabis plant containing more than 0.3 THC. CBD is defined under MMCREA as the substance derived from marijuana with a THC level greater than 0.3%.

The MMCREA also removes the federal prohibition on doctors discussing the benefits and harms of medical marijuana with patients, allows the import and export of marijuana for research purposes, and requires federal agencies to report to Congress on the therapeutic and harmful effects of marijuana and on the barriers to future research.

The full text of the MMCREA can be found here, and a summary of some key provisions of the bill is listed below:

Section 101: Streamlined Approval of Research Applications

Under Section 101 of MCCREA, the US Attorney General "shall register a practitioner to conduct research with marihuana"; provided the below criteria are met:

- The research protocols must have been reviewed and approved by:
    - The US Secretary of Health and Human Services, pursuant to FDA regulations regarding INDs and clinical trials;
    - A federal agency that funds scientific research, such as the National Institutes of Health; or
    - Pursuant to regulations promulgated by the Drug Enforcement Administration (DEA) regarding research protocols regarding Schedule I substances.
- The applicant must demonstrate to the Attorney General's satisfaction that there will be adequate safeguards preventing marijuana from being diverted to purposes other than legitimate medical or scientific use.

The Attorney General will have no discretion to deny an application, *unless* they decide that registration is against the public interest. The five factors that determine public interest are drawn from CSA:

- The recommendations of the relevant state licensing board or professional disciplinary authority, if applicable;
- The applicant's experience in dispensing or conducting research using controlled substances;
- The applicant's drug-related federal or state conviction record;
- The extent to which the research protocols comply with state, federal, or local laws; and
- The public's health and safety.

These provisions only apply to research applications by practitioners – defined under the CSA as a person licensed to "distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research."

Within 60 days of receiving an application, the Attorney General must either give approval or request supplemental information. After receiving supplemental information, the Attorney General must either approve or deny the application within 30 days.

Section 103: Additional Manufacturing Licenses

Between 1968 and 2021, the federal government only allowed one entity – the National Center for Development of Natural Products at the University of Mississippi – to cultivate research-grade cannabis. Since then, six more organizations have been granted bulk manufacturing licenses.

Under MMCREA's Section 103, if the Attorney General has placed a notice in the Federal Register to increase the number of registered bulk manufacturers, they are then obliged to act on any completed application within 60 days of receipt. The completed application must document that:

- The requirements listed in the Federal Register notice are fulfilled;
- All MMCREA requirements are satisfied;
- The applicant will only transfer or sell the cultivated marijuana to properly registered researchers for use in preclinical research or in a clinical investigation pursuant to an IND exemption;
- Any transfer or sale of the manufactured marijuana will have prior, written consent from the Attorney General;
- The applicant has otherwise completed the CSA's application and review process for the bulk manufacture of Schedule I substances;
- There will be adequate measures for securely storing and handling the marijuana; and
- The applicant has received the necessary state-level authorizations for all operations.

The Attorney General has considerably more discretion over bulk manufacturing licenses compared to research applications. First, the approval process outlined above is only triggered when the Attorney General decides to give notice in the Federal Register. While Section 104 of MMCREA requires that the Attorney General annually report to Congress regarding steps to ensure an adequate and uninterrupted supply of marijuana for research purposes, this reporting obligation does not seem to be tied to Section 103. Second, whereas research applications may only be denied due to public interest, there is no such requirement for denials of manufacturing license applications.

As is the case for research applications, the Attorney General must give approval or request supplemental information within 60 days, and must either approve or deny the application within 30 days of receiving supplemental information.

Clinical Trials and Development of New Drugs

The MMCREA facilitates trials and development of new FDA-approved drugs that use marijuana or CBD. Section 101 provides for the approval of research protocols that are part of FDA-compliant clinical trials and IND studies. Likewise, Section 103 allows manufacturers to transfer or sell research-

grade marijuana for use in preclinical research or in IND trials.

Further, Section 202 of MMCREA directs the Attorney General to register any applicant seeking to manufacture or distribute CBD or marijuana for the purposes of commercially producing an FDA-approved drug. These registered parties are then permitted to manufacture, distribute, dispense, or possess marijuana or CBD either for medical research for drug development (such as clinical trials), or for commercial production.

Conclusion

The passage of MMCREA comes after several abortive legislative proposals to loosen restrictions on medical marijuana research (*e.g.*, the Marijuana Effective Drug Studies Act of 2016). It is possible (albeit not certain or likely) that MMCREA's success will become part of a broader push for federal marijuana reform (*i.e.*, the SAFE Banking Act) before the Republican Party takes power in the House in January 2023. Accordingly, ArentFox Schiff continues to actively monitor the state of play for cannabis legislation at the federal level and around the country.

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