MARIJUANA EFFECT DRUG STUDIES (MEDS) ACT OF 2016
ONE-PAGE SUMMARY

Background:

Marijuana and its compounds have shown promise in treating a variety of diseases. Because marijuana is a Schedule I substance under the Controlled Substances Act, however, it is subject to significant restrictions on its use. These restrictions inhibit research to determine the medical benefits of marijuana and its compounds. In particular, medical researchers are allowed to work with marijuana only after completing an onerous and at times redundant application process with the Drug Enforcement Agency (DEA). This drawn-out process can delay research by years on end and in some cases dissuade researchers from beginning study in the first place.

Medical researchers report that there are three primary sources of delay in obtaining regulatory approval to research marijuana:

- DEA requires a full, independent review of the research protocol, even if the protocol has already been reviewed and approved by the Food and Drug Administration (FDA), National Institutes of Health (NIH), or another federal agency;
- DEA often requires security measures that are not grounded in statute or regulation; and
- Whenever a researcher amends or supplements a research protocol, the researcher must restart the DEA approval process from scratch.

Another barrier to effective research is the inadequate supply of marijuana that may be used for research purposes. DEA currently limits researchers to marijuana grown by the National Institute on Drug Abuse (NIDA) at a single facility at the University of Mississippi. This single supplier is unable to provide sufficient amounts or specific strains needed for approved medical research. Additionally, current law does not permit marijuana to be manufactured for the production of an FDA-approved drug.

Key Provisions:

The MEDS Act would streamline the approval process for medical marijuana research while retaining important safeguards to prevent diversion or abuse of marijuana and its compounds:

- Researchers would be required to demonstrate that their research protocol has been reviewed and approved by a federal agency such as FDA (for human or clinical research) or NIH (for non-human research), but would no longer be required to undergo a separate research protocol review with DEA. DEA's review process would focus on safety and risk of diversion—areas within DEA's core mission.
- Researchers would also be required to demonstrate that sufficient security measures are in place to guard against diversion or abuse, but would no longer be required to put in place measures that go beyond current DEA regulations. Rather, the MEDS Act would codify current regulations requiring that Schedule I substances be kept in a "securely locked, substantially constructed" cabinet.
- DEA would have 60 days to respond an application to conduct research on marijuana. Under current law, there is no deadline for DEA to respond to such an application.
- Researchers would be permitted to amend or supplement their research protocols following review by the federal agency funding their research without having to reapply to DEA. DEA would have 30 days to object to any such amendment or change. Under current law, any change to a research protocol requires the researcher to repeat the DEA approval process from scratch.

In addition, the MEDS Act would instruct DEA to license marijuana manufacturers for purposes of legitimate medical research and production of FDA-approved drugs, unless an application is inconsistent with the public interest.