

## Research Provisions and State Medical Cannabis Laws

Federal policies make it difficult to conduct clinical research on medical cannabis. Hurdles include the lack of adequate funding and unique obstacles to gaining approval. Clinical research can only use cannabis produced at the University of Mississippi on contract with the federal government — and it is notoriously difficult to access that cannabis. While there is ample evidence that medical cannabis is a safe and effective treatment for several conditions, there are some conditions that cannabis might alleviate that have not been subject to much — if any — research.

State medical cannabis laws' primary goal should be to provide patients with legal protections and safe access to cannabis so that they may alleviate their suffering. However, states may also wish to facilitate research. They must carefully craft such provisions to avoid rendering the entire program unworkable and driving up costs. Research provisions should be supplemental to a state-based system for access, rather than seeking to serve as a substitute for such a program.

**Study-based laws as substitutes for comprehensive programs are unworkable.** Since the 1980s, at least 26 states have enacted therapeutic research programs that were meant to provide patients with access to cannabis. Federal policies regarding clinical research were more relaxed in the 1980s, and a few hundred patients in seven states received cannabis, typically for the side effects of chemotherapy, before these programs closed down.

Federal policies on cannabis research became far stricter by 1999. Getting federal approval for a study can take many years, and the research typically must be conducted in a hospital — meaning patients are not free to remain in their homes. In addition, federally approved medical cannabis studies are extremely costly, are almost always short-term, and typically apply to a single condition. Many patients receive a placebo. If a primary goal is to provide serious ill patients access to cannabis, these programs fail miserably.

In 2013, Maryland became the only state since 1990 to enact a clinical research study as a medical marijuana law. Unsurprisingly, the program never materialized. In 2014, the state legislature abandoned that ineffective law and replaced it with a law that allows in-state growers to provide medical cannabis to patients either directly or via dispensaries.

## States can provide funding for research.

At least two states have provided substantial funding to facilitate research in recent years. In 1999, California provided \$8.7 million in funding for the Center for Medicinal Cannabis Research, which has conducted the bulk of the placebo-

controlled recent research into the efficacy of medical cannabis in recent years. The funding recently ran out. In 2015, Colorado approved \$9 million in grants for medical cannabis research.

Both states realize that rigorous research *supplements* access-based programs; it is not a substitute for them. The research conducted in California only resulted in about two weeks' access of cannabis to less than 250 patients.

## States could collect data at dispensaries.

Another possibility is to provide for the collection of data from patients *at dispensaries* to increase the knowledge of how different strains and preparations are working for different conditions. This would be observational research, not clinical research — which would have to use federal marijuana. While it would not result in the kind of "gold standard" data that comes from placebo-controlled clinical trials, it is still valuable information.

This type of data collection should be voluntary for patients, and the data could be made available to researchers. Any such provision should be crafted in a way that makes the cost to the state and dispensaries modest. This would keep the data collection very simple and would not require an onerous expense for dispensaries or the state — which would be passed on to patients — nor would it require scientific expertise at dispensaries.

We are not aware of any state that includes this kind of data collection in a state program. Minnesota requires *physicians* who write recommendations to collect data, and requires it to be collected by the health department. We strongly advise against that approach, which is mandatory for patients and has driven up administrative costs tremendously. It is also expected to reduce physicians' participation by requiring them to collect a lot of data to participate.

## Conclusion

In addition to setting up a licensing system that provides in-state access to medical cannabis, states can facilitate research, such as by providing funding to researchers with approved clinical trials. They must not seek to combine a medical cannabis program with clinical research — such programs fail to materialize due to federal law. States should also avoid cumbersome requirements on dispensaries and patients that will merely drive up costs and reduce participation. All proposals should be run by experts to ensure they are feasible in light of federal law.

<sup>&</sup>lt;sup>1</sup> See: Igor Grant, et al. "Report to the Legislature and Governor of the State of California presenting findings pursuant to SB847 which created the CMCR and provided state funding." UC San Diego Center for Medicinal Cannabis Research, February 10, 2010. <a href="http://www.cmcr.ucsd.edu/images/pdfs/CMCR\_REPORT\_FEB17.pdf">http://www.cmcr.ucsd.edu/images/pdfs/CMCR\_REPORT\_FEB17.pdf</a> See: "Approved medical marijuana research grants," Colorado Department of Public Health & Environment: https://www.colorado.gov/pacific/cdphe/approved-medical-marijuana-research-grants