

August 29, 2023

Governor Brian Kemp 206 Washington St SW Atlanta, GA 30334

Dear Governor Kemp,

SAM Action, Inc., a leading non-partisan drug policy organization focused on raising awareness about the harms of marijuana, is concerned by the Georgia Board of Pharmacy's approval of rules that would allow independent pharmacies to sell THC oils. These rules, if signed into law, would allow at least 100 new marijuana stores to open without input or approval from community members. Many of these communities do not want marijuana sold in their communities. In order to protect public health and safety, we respectfully urge you not to sign these rules into law.

While three other states with medical marijuana programs allow or require pharmacists to dispense marijuana products from "medical marijuana" dispensaries, there is no state that allows licensed pharmacies to dispense any marijuana products except for those approved by the FDA. The FDA states:

"To date, the FDA has not approved a marketing application for cannabis for the treatment of any disease or condition. The agency has, however, approved one cannabis-derived drug product: Epidiolex (cannabidiol), and three synthetic cannabis-related drug products: Marinol (dronabinol), Syndros (dronabinol), and Cesamet (nabilone). These approved drug products are only available with a prescription from a licensed healthcare provider. Importantly, the FDA has not approved any other cannabis, cannabis-derived, or cannabidiol (CBD) products currently available on the market."

Marijuana's status as a Schedule I drug means it has a high risk of addiction and it does not have a widely accepted medical use. Marijuana contains hundreds of chemical components, or cannabinoids, at varying levels. The drugs listed above are isolated cannabinoids administered under the supervision of a doctor who can work with patients to weigh potential benefits and risks, these medications are not marijuana. These 4 prescription drugs are available in all states regardless of marijuana's legal status in the state.

The proposed rules would take the unprecedented step of selling THC oils, which have not been approved by the FDA, in addition to selling these four FDA approved products to patients with the approved conditions. Unlike medications, these oils are not tested by the FDA for safety or



quality; no independent body verifies that these products contain what they say they contain at the levels that they claim.

The manufacturing of prescription medications is and should be a rigorous process where pharmaceutical companies are accountable to the safety requirements of the FDA. Unlike with prescription medications, consumers of this THC oil could get different doses of THC depending on the batch, they could be exposed to unhealthy levels of pesticides, have a greater risk pf contamination, and there exists no body that is charged with the assembly of any adverse effects on consumers. Instead of putting consumers and the FDA on offense, this measure puts them both on defense.

There also exists the risk that consumers could confuse FDA approved drugs for the non-approved THC oil. Epidiolex is often used to treat rare seizure disorders in children, and well-meaning parents could unintentionally administer this unapproved oil to treat their children's disorder. In this case, the child could face long-term consequences both from improper dosage or contamination and from lack of treatment.

The distinction between marijuana and medicine must be made clear. The FDA does not endorse or verify any of the claims made about marijuana or cannabis-derived oils outside of the 4 prescription medications listed above, but their sale in a licensed pharmacy implies the FDA's endorsement. The FDA added, "There has been no FDA review of data from rigorous clinical trials to support that these unapproved products are safe and efficacious for the various therapeutic uses for which they are being used." This conflict would be both dangerous and confusing for consumers.

The rule passed by the Georgia Board of Pharmacy would increase access to a drug with a high potential for abuse and that has not been approved by the FDA for the treatment of any disease or condition. It is also worth recognizing that this policy is being lobbied for not by patients, but by the for-profit marijuana industry that stands to benefit from its passage. We respectfully urge you to reject the Georgia Board of Pharmacy's rules, which are out of step with federal law, dangerous and confusing for consumers, and would make Georgia the only state in the nation to allow independent pharmacies to sell THC oils.

Respectfully,

Kevin A. Sabet, PhD

President and Co-Founder SAM Action, Inc.

Kevin Sabet

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