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Discrepancies Between Federal and State Marijuana Laws Pose Significant Barriers to Research – New Guidance Needed

The Problem:
A number of states are working to facilitate research on the therapeutic benefits of marijuana and its constituent compounds and some have allocated funding from tax revenue from cannabis dispensaries for research. However, universities and researchers are concerned that if they conduct research using cannabis products from retail or state dispensaries (even if they aren’t using federal funds) that they may be risking their DEA licenses or federal funding. In addition, there is a need for reform in the regulation and process for cannabis product testing. Federally funded researchers are interested in characterizing state-legal cannabis products to evaluate the chemical composition, consistency, and label accuracy of these products. However, at this time, cannabis products cannot be purchased with federal funds, analytical labs with a Schedule I license cannot receive cannabis products from a non-federal source, and labs without a Schedule I license cannot obtain the proper reference materials with which to conduct valid analytical testing. A pathway is needed to allow researchers to purchase retail cannabis products, transport them across state lines if necessary, and to bring these products into the federal chain of custody for drug accountability under their Schedule I licenses.

Understanding the characteristics of the marijuana that is being dispensed, including the potency (i.e., amount of tetrahydrocannabinol [THC] in the plant) and concentration of other components (e.g., CBD), is critical for studying the impact of potential positive and negative consequences of medical marijuana on individual and public health and can lead to more refined cannabinoid medication development through identification of target chemical constituents associated with unique behavioral or physiological effects. Further, human laboratory studies using products available from dispensaries, and which meet federal drug manufacturing regulations, would provide a much more realistic/accurate evaluation of the potential therapeutic effects: potential adverse health consequences of use; physiologic and subjective effects; patterns of self-administration; and the pharmacological properties of the range of inhaled, oral, and transdermal products currently being dispensed or under development.

Suggested Language for a Memo to Protect Scientists:
On February 14, 2014, the Department of Justice issued guidance instructing Department attorneys and law enforcement to focus on eight priorities in enforcing the Controlled Substances Act against marijuana-related conduct. With the growing need to understand the basic pharmacology and potential therapeutic benefits of cannabinoids as well as their deleterious effects, the Department of Justice is extending that guidance to facilitate and streamline the conduct of scientific research in states where cannabis or cannabis extracts have been legalized for medicinal or non-medical (i.e. “recreational”) use (consistent with the laws of the individual states).

As such, Department attorneys and law enforcement will provide a covenant not to prosecute, scientists with a current DEA Schedule I license, conducting clinical or basic research on cannabis (or cannabis extracts) as long as they are in compliance with federal laws governing research (e.g., FDA regulations for Good Manufacturing Practices for Drugs and IND research, HHS Common Rule, Animal Welfare Act, etc…), and as long as their laboratory doesn’t
become a source of diversion with implications for the DOJ enforcement priorities laid out in Deputy Attorney General Cole’s Memo of February 14, 2014. Further, these same investigators will be held harmless for the transport/shipment of cannabis products within and across state lines for forensic analytic testing at Schedule I approved testing laboratories in conjunction with that research as long as the products are inventoried upon purchase by the researcher or designated staff and products are transferred between DEA licensed entities using DEA Form 222.