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Report on Marijuana Research

Report to Congress

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16. Abstract

This report was prepared in accordance with Section 25026 (Report on Marijuana Research) of the Infrastructure Investments and Jobs Act (IIJA), Pub. L. 117-58, which requires the U.S. Department of Transportation to submit a report to Congress describing methods for increasing and improving scientific researcher access to marijuana, establishing a national clearinghouse to distribute marijuana for research purposes, and for facilitating researcher access to marijuana. Congress also requested information on statutory and regulatory barriers to conducting scientific research on cannabis and driving.

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Report On Marijuana Research

Background

Section 25026 of the Infrastructure Investment and Jobs Act (IIJA), Pub. L. 117-58, requires the Department of Transportation to produce a report on marijuana research:

> SEC. 25026. REPORT ON MARIJUANA RESEARCH. (a) DEFINITION OF MARIJUANA. — In this section, the term ‘‘marijuana’’ has the meaning given the term in section 4008(d) of the FAST Act (Public Law 114–94; 129 Stat. 1511). (b) REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary, in consultation with the Attorney General and the Secretary of Health and Human Services, shall submit to the Committees on Commerce, Science, and Transportation and the Judiciary of the Senate and the Committees on Transportation and Infrastructure and the Judiciary of the House of Representatives, and make publicly available on the website of the Department, a report that—
>
> (1) describes methods for, and contains recommendations with respect to—
>
> (A) increasing and improving, for scientific researchers studying impairment while driving under the influence of marijuana, access to samples and strains of marijuana and products containing marijuana that are lawfully available to patients or consumers in a State on a retail basis;
>
> (B) establishing a national clearinghouse to collect and distribute samples and strains of marijuana for scientific research that includes marijuana and products containing marijuana lawfully available to patients or consumers in a State on a retail basis; and
>
> (C) facilitating, for scientific researchers located in States that have not legalized marijuana for medical or recreational use, access to samples and strains of marijuana and products containing marijuana from the clearinghouse described in subparagraph (B) for purposes of research on marijuana-impaired driving; and
>
> (2) identifies, and contains recommendations for addressing, Federal statutory and regulatory barriers to—
>
> (A) the conduct of scientific research on marijuana impaired driving; and
>
> (B) the establishment of a national clearinghouse for purposes of facilitating research on marijuana-impaired driving.

The Department of Transportation (DOT) established a collaborative relationship with the Department of Justice (DOJ) and the Department of Health and Human Services (HHS) to prepare a report that meets the requirements of Section 25026. Because these departments are not the only ones within the Federal government with responsibilities related to the requirements of Section 25026, DOT gathered additional information from the United States Department of Agriculture (USDA), the Department of Commerce (Commerce), the Department of State (State) and the Office of National Drug Control Policy (ONDCP). Table 1 provides an overview of authorities and responsibilities related to cannabis and cannabis research of each of the departments or agencies consulted for this report. Other departments or agencies, such as Department of Treasury’s Financial Crimes Enforcement Network, the Department of Health and

Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA) and others, may have responsibilities related to cannabis that are outside the scope of this report.

Table 1. Descriptions of Departmental and Agency Authorities and Responsibilities Related to Cannabis and Cannabis Research

Department	Sub Agency	Overview of Authorities and Role in Research
Agriculture (USDA)		Section 10113 of the Agriculture Improvement Act of 2018, Pub. L. 115-334, (Farm Bill of 2018) authorized the production of hemp and removed hemp and hemp seeds from the Drug Enforcement Administration's (DEA) schedule of Controlled Substances under the Controlled Substances Act, 21 U.S.C. § 801 et seq. and 21 U.S.C. § 841 et seq. (CSA). The U.S. Domestic Hemp Production Program establishes federal regulatory oversight of the production of hemp in the U.S. By definition, hemp has low THC (no more than 0.3% THC on a dry weight basis).
Commerce	National Institutes for Standards and Technology (NIST)	NIST manages a measurement services program for forensic and cannabis testing laboratories to ensure consistency of practice between laboratories across the country. The program supports external laboratory work to distinguish hemp from marijuana, quality control for safety and ingredient labeling, and research products related to clinical trials of efficacy of cannabinoids.
Health and Human Services (HHS)	National Institute on Drug Abuse (NIDA)	NIDA is the primary NIH component supporting research on marijuana. NIDA provides cannabis and cannabinoid products for research purposes through the NIDA Drug Supply Program. Information on ordering guidelines is available at https://nida.nih.gov/research/research-data-measures-resources/nida-drug-supply-program-dsp/nida-drug-supply-program-dsp-ordering-guidelines/ordering-guidelines-0
	National Center for Complementary and Integrative Health (NCCIH)	NCCIH is the lead NIH component supporting scientific research on complementary and integrative health approaches. NCCIH explores the possible therapeutic uses of cannabis and its constituent compounds, which is a subset of cannabis related research.
	Food and Drug Administration (FDA)	FDA provides guidance on quality considerations for clinical research related to cannabis and cannabis-derived compounds[i] [ii] and guidance on evaluating drug effects on the ability to operate a motor vehicle.[iii]

Department	Sub Agency	Overview of Authorities and Role in Research
		FDA manages the Investigational New Drug (IND) process, which gives researchers a path to follow that includes regular interactions with the FDA to support efficient drug development while protecting the patients who are enrolled in the trials. An IND includes protocols describing proposed studies, the qualifications of the investigators who will conduct the clinical studies, and assurances of informed consent and protection of the rights, safety, and welfare of the human subjects. The FDA reviews the IND to ensure that the proposed studies, generally referred to as "clinical trials," do not place human subjects at an unreasonable risk of harm.
Justice (DOJ)	Drug Enforcement Administration (DEA)	DEA regulates entities that grow and distribute cannabis for research. In 2020, DEA finalized new regulations pertaining to applications by entities seeking to become registered with DEA to grow marijuana as bulk manufacturers for research purposes. Researchers will work directly with the DEA to obtain cannabis for research purposes from these growers.[iv]
	National Institute of Justice (NIJ)	NIJ funds research, development, and technology assistance. NIJ also assesses programs, policies, and technologies.
Office of National Drug Control Policy (ONDCP)		ONDCP coordinates drug policy activities, provides national leadership, and provides coordination among national drug program agencies.
Department of State (State)		The Department of State is responsible for ensuring treaty compliance associated with drug movement across international borders following UN drug control conventions (1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic substances). The conventions specify exceptions and requirements under which parties make drugs available. Research is one of those exceptions.
Department of Transportation (DOT)	National Highway Traffic Safety Administration (NHTSA)	NHTSA's mission is to save lives and prevent injuries that result from motor vehicle crashes. Under 23 U.S.C. § 403, NHTSA conducts research and program activities to understand and prevent impaired driving. Research related to drugs and traffic safety explores the prevalence of drugs and alcohol and other drugs among road users,

Department	Sub Agency	Overview of Authorities and Role in Research
		on detecting impairment among drivers, and on exploring crash risk associated with drug presence.
	Office of Drug and Alcohol Policy and Compliance (ODAPC)	ODAPC advises the Secretary of Transportation on national and international drug testing and control issues and is the principal advisor to the Secretary on rules related to the drug and alcohol testing of safety-sensitive transportation employees in aviation, trucking, railroads, mass transit, pipelines, and other transportation industries.

Under the CSA, researchers who wish to investigate the effects of cannabis on human performance must be licensed by DEA to do so at sites that have site-specific DEA investigator registration.[v] In general, the process is as follows:

1. The researchers establish a study design and submit it to their local institutional review board (IRB) for the protection of human subjects.
2. The researchers obtain the product from a DEA-licensed site, typically from NIDA through its Drug Supply Program.
3. The researchers submit an IND application to FDA. As part of this application, testing must be completed to ensure the substances to be used are free from contaminants and that the dosing will be consistent, and that risk mitigation is clearly articulated.
4. The researchers submit revisions of the protocols that result from the IND application to the IRB for inclusion and approvals.
5. The researchers request approval from DEA to conduct the study. Approvals may require DEA or State DEA inspections. If the substance under investigation qualifies as hemp under the Farm Bill of 2018 (0.3% THC or lower by weight), DEA approval is not required.

This process can be time-consuming (a minimum of six months), but the steps are not necessarily barriers to conducting research. Steps 1, 3, and 4 are designed primarily to protect study participants from adverse effects of exposure to hazards that are introduced in the study process, Step 5 is designed primarily to prevent the diversion of substances, and Step 2 serves both goals.

Approach to this Report

In NHTSA's 2017 *Report to Congress on Marijuana-Impaired Driving,*[vi] Compton described a review of research on the effects of marijuana use on driving, and the feasibility of developing an impairment standard for drivers under the influence of marijuana. The report described presence of THC or metabolites vs. impairment, lack of correspondence between THC levels in biosamples and objective impairment, the effects of different strains of marijuana with regard to driver impairment, and other traffic safety related concerns. While other research has been conducted since that report, the conclusions in it are still relevant and correct, and the Department sees it as the primary reference for understanding how to study impairment and

prevalence of cannabis among road users. In April 2023, NIDA published an updated fact sheet, *Does marijuana use affect driving?*[vii], that provides a high-level summary of research findings related to cannabis-induced driving impairment. In *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*[viii], a panel of researchers and experts convened by the National Academies of Sciences, Engineering and Medicine (NAS) identified challenges and barriers to conducting cannabis research. The Department, in collaboration with DOJ and HHS, reviewed these publications to explore the identifiable barriers to answer the specific Congressional questions identified in the statute. These departments also conducted reviews to identify specific limitations that might be considered barriers to establishing a clearinghouse to facilitate research on marijuana-impaired driving.

In late 2022, Congress passed the Medical Marijuana and Cannabidiol Research Expansion Act (Pub. L. 117-215).[ix] This law requires DOJ to provide recommendations related to overcoming barriers to conducting research involving cannabis and the effects of delta-9 tetrahydrocannabinol (THC) levels on cognitive abilities such as those required to operate motor vehicles and the barriers to cannabis research. The DOJ recommendations are likely to influence research practices in all states, including those that have not legalized cannabis as specified in section 25026 of BIL. The implementation and associated rulemaking plans for this law are under development by the relevant departments. These plans are not reflected in this document; however, Purcell et al. (2022) prepared a detailed analysis of potential implementation challenges and opportunities associated with research under that law.[x] In August 2023, HHS recommended to DOJ that cannabis be rescheduled from Schedule I of the Controlled Substances Act (no known therapeutic use) to Schedule III, a less restrictive category reserved for drugs with a moderate to low potential for physical or psychological dependence.[xi] Finally, there is substantial ongoing research on cannabis and on how impairment might be detected or understood. Because the science in this area is not settled, new findings may be released at any time. Considered together, these factors complicate the longevity of the findings of this report.

Methods for increasing researcher access to samples

On December 18, 2020, DEA finalized new regulations (85 FR 82333) pertaining to applications by entities seeking to become registered with DEA to grow marijuana as bulk manufacturers for research purposes. Under these and other applicable regulations, applicants are responsible for demonstrating they have met various requirements, including requirements to possess appropriate authorization under State laws to grow cannabis for research purposes, document that their customers are licensed to perform research, and employ adequate safeguards to prevent diversion.[xii] As of October 2023, 8 bulk manufacturers are registered to produce cannabis for more than 575 DEA-licensed researchers;[xiii] however, these products may not be available for traffic safety research and these researchers may not be conducting traffic safety research (e.g., because they are pursuing medicinal research).

To improve researcher access, DEA and NIDA provide step by step information on how to register to conduct research using cannabis[xiv] or obtain research materials[xv, xvi], respectively. Both organizations also provide customer service contacts to support their missions in this area.

In May 2023, the National Center for Complementary and Integrative Health (NCCIH) published a project concept review regarding a resource center for cannabis and cannabinoid research.[xvii] The activities of the proposed project include facilitating connections to high-quality research

products and to administering seed funding for license support and proposal development. In a September 2023 NAS public meeting on the Public Health Consequences of Changes in the Cannabis Policy Landscape project, an NCCIH speaker indicated the agency's intention to issue a notice of funding opportunity (NOFO) to establish this resource center.[xviii] The NOFO was issued on October 26, 2023.[xix]

While the above resources are intended to increase researcher access to cannabis, it is important to recognize the constraints under which current researchers operate as they investigate the impairing effects of cannabis. For example, under 21 CFR § 1301.13, federally funded researchers are prohibited from analyzing products available in State-authorized dispensaries. Developing a process for researchers to access and test real-world products available in State-authorized dispensaries will be important to developing a clear understanding of the relevant traffic safety impacts of cannabis use by members of the public. Other research process constraints are highlighted in Table 2.

Table 2. High-level summary of constraints to research on cannabis

CONSTRAINT	**Description**
Lack of researcher access to real-world cannabis products limits our understanding of real-world use and exposure	Federally funded researchers are prohibited under the CSA and 21 CFR § 1301.13 from chemically analyzing products available in State-authorized dispensaries. Researchers must rely on participants to self-report or provide photos of unverified product labels from dispensaries which are inconsistently regulated across jurisdictions. Understanding the characteristics of products on the market - including the amount of THC, the concentration of other cannabinoids and components, and potential toxins such as pesticides - is important for determining and differentiating characteristics responsible for health effects that include traffic safety.
University risk management requirements are difficult to overcome	To legally obtain cannabis for research purposes, researchers must take many steps to assure Federal and State regulators that the substance will be obtained legally and handled appropriately. This restriction means that if a lab obtains and studies cannabis from a source other than a federally sanctioned one, *all* other Federal funding is at risk; as a result, universities may choose not to conduct cannabis research. Establishing a cannabis laboratory also requires extensive facilities and operational costs that must be assumed up-front. For example, cannabis samples must be secured in a vault that is not movable (anchored to the floor). The vault must have a security system to monitor the door to the vault and otherwise restrict facility access. The laboratory must have appropriate facilities to support pharmacy-level dosing capability, as well as facilities for drawing and storing research participant biological samples, facilities to conduct psychometric and other testing for subjects, and facilities for safely and securely dosing subjects. All of these must be in place to obtain Federal and State licenses to obtain cannabis for

CONSTRAINT	Description
	research purposes, but investing in these facilities does not guarantee that a laboratory will be able to obtain the appropriate licenses. Universities may choose not to assume that risk.
Researchers using mobile laboratories don't know what is being tested, so the research leaves many questions open	In States that allow the public to use marijuana, some researchers use mobile laboratories to conduct research. These laboratories are typically based in a van or small RV and are used to collect biological samples (e.g., blood, oral fluids) from study participants and conduct psychomotor tests near a study participant's home. Study participants come to the mobile lab, provide pre-use biological samples to the researchers, show the researchers the substance that they have purchased for themselves, then return to their homes to consume the substance. Once they have consumed the substance, the participants return to the mobile lab on foot to provide additional samples and tests. While studies of this nature are extremely valuable and contribute to our understanding of cannabis in a real-world setting, the researchers and participants do not know the actual dose or substance the participants consume, so the results of these studies may not be accurate. These significant limitations suggest that policy should not be based solely on the findings of this type of investigation.
The lack of easy-to-use information on how to become a cannabis researcher and establish a laboratory makes it difficult for new research entrants	The Federal and State requirements to obtain permissions from Federal and State agencies and to obtain cannabis research substances are posted on different websites and in different agencies. The DEA maintains a research manual that covers the high-level approach to obtaining the approvals needed for permissions, but researchers must be willing to persist in meeting the requirements of each layer of Federal and State regulations and seek support from institutional partners. Often, other researchers who have gone through the process are a valuable source of information, but there may be little incentive to collaborate with future grant competitors.
Ensuring research participant safety will remain a challenge	Safety standards associated with retail cannabis products are inconsistent and vary by State, so they may contain contaminants such as pesticides or other health threats. National standards would help to protect users of these legal products.[xx] Protecting human research participants is a fundamental requirement of any investigation. This tension between the need to know what the public is consuming and how it affects users and the imperative to prevent undue exposure to toxins and other substances that might influence performance will need careful exploration. If researchers are investigating substances that are regulated by FDA rather than DEA (e.g., CBD and other products with 0.3 % or

CONSTRAINT	Description
	less THC), they must employ the Investigational New Drug (IND) process outlined by FDA. In either case, each individual product to be used in testing is assessed on a case-by-case basis to ensure participant safety.

Methods related to establishing a clearinghouse

In December 2020, the DEA published the final rule *Controls to Enhance the Cultivation of Marihuana for Research in the United States.*[xxi] This final rule amended DEA regulations to facilitate the cultivation of cannabis for research purposes and other licit purposes pursuant to the Controlled Substances Act, 21 U.S.C. § 801 et seq. and 21 U.S.C. § 841 et seq. Under this rule, new manufacturers (growers) may register their products for transfer to researchers (buyers) through the DEA. This approach ensures that production is consistent with the public interest and that the United States meets the obligations related to diversion under the Single Convention on Narcotic Drugs, 1961.[xxii]

As noted above, Congress passed the *Medical Marijuana and Cannabidiol Research Expansion Act* (Pub. L. 117-215) in 2022, and plans for its implementation are currently under development. The Secretary of HHS recommended that cannabis be rescheduled from Schedule I to Schedule III and, according to a September 2023 Congressional Research Service (CRS) analysis[xxiii], rescheduling may result in an increase in demand for FDA oversight for medical marijuana and related products.

A first step to establishing a clearinghouse to collect and disseminate cannabis samples is the proposed NCCIH Resource Center for Cannabis and Cannabinoid Research. The purpose of the proposed initiative is to "reduce barriers to conducting research on cannabis and its constituents as well as to enable researchers to successfully generate more rigorous scientific evidence around the potential clinical uses of cannabis products. The Center is also expected to be a focal point for researchers entering the cannabis research space and to support the development and establishment of research tools and studies that will improve upon and eventually change the landscape of cannabis research."[xxiv]

Facilitating research with an emphasis on marijuana-impaired driving

As of October 2023, any researcher using Federal funds, regardless of the legal status of cannabis in the State in which they operate, must be registered with DEA and their State to obtain licenses and permissions to conduct research using cannabis under 21 CFR § 1301.13. As discussed above, there are extensive requirements for researchers to obtain those licenses, including having a secure facility and appropriate pharmacy and testing facilities on site. Rescheduling cannabis may ease researcher access to products.

Currently, the best way to facilitate research on cannabis use and traffic safety is to sponsor (fund) such research. Both NHTSA and NIDA sponsor specific research studies in this area. NHTSA funds research on cannabis impairment, detection, and prevalence in a road traffic safety setting; similarly, NIDA funds research on cannabis impairment and detection.

NHTSA research in this area includes a scoping review to determine how drug researchers implement FDA guidance for evaluating drug effects on operating a motor vehicle and a laboratory investigation to examine the feasibility of a field test for marijuana impairment. Broader research topics include examinations of the prevalence of drug presence among road users, detection cues for law enforcement to identify drug-impaired drivers, and ways to improve the data submitted to the Fatality Analysis Reporting System. Detailed descriptions of these projects can be found on the Transportation Research Board's Research in Progress database at https://rip.trb.org/.

NHTSA also sponsors Small Business Innovative Research (SBIR) projects related to oral fluid and breath analysis to detect recent cannabis use. If the SBIR projects succeed, they will offer non-invasive methods to quantify a driver's THC at the roadside. These promising tools may result in commercial products that can be used in a traffic law enforcement setting. This could aid in adjudication of impaired driving cases where cannabis use is suspected by documenting time-sensitive information about the amount of THC present in the suspected impaired driver.

NIDA is currently funding research on improved detection methods. Some examples include:

- Development of portable devices designed to detect impaired driving through psychomotor and oculomotor measures and blood biomarkers (R01DA049800-02).
- Development and testing of a cannabis breath analyzer to provide rapid, non-invasive, point-of-use detection of cannabis use (R44DA041225-03)
- Combining smartphone monitoring of driving behavior with self-report and saliva samples to examine the effects of cannabis on driving among medical cannabis patients (R21DA054614-01A1).

It should be noted that this research is discrete from workplace drug testing. Research is investigatory whereas workplace testing of employees in safety-sensitive positions is designed to ensure workplace safety.

Statutory and Regulatory Barriers to Conducting Scientific Research on Cannabis and Driving

Human subjects protections and diversion prevention: As stated above, the *Medical Marijuana and Cannabidiol Research Expansion Act* was passed into law in late 2022 and is currently being implemented. Thus, the rules under which researchers must operate may change. Until such changes are enacted, the existing rules remain in place and bring specific challenges to conducting research. The steps below were identified in the 2017 NAS synthesis report[xxv] and are relevant to traffic safety research that will exist until new rules are established.

At a minimum, the following steps are required:

1. Apply for initial local IRB approval for research study
2. Submit IND application to FDA
3. Obtain a Letter of Authorization from NIDA
4. Apply to DEA for registration and site licensure

5. Submit full package above to FDA for review
    i. FDA review ensures no unreasonable risk to participants and holds approval until concerns resolved
    ii. Some States require a controlled substance certificate or registration or additional clearances from the State prior to approval
6. Submit approved package to DEA for registration and site licensure
    i. If a Schedule I substance, DEA requires a research protocol regarding safeguarding the substance
    ii. Local DEA officials may inspect/investigate prior to approval
7. Obtain IRB approval of the cleared protocols to protect participants in human subjects research

As indicated earlier in this report, these steps are not necessarily barriers to conducting research. Each serves the purpose of protecting research participants and/or preventing diversion of cannabis to unauthorized individuals.

Some regulatory relief from these steps could be achieved if cannabis were removed from Schedule I of the Controlled Substances Act, which is reserved for drugs that have "no currently accepted medical use."[xxvi] In October 2022, President Biden requested the Attorney General and the Secretary of Health and Human Services to review how cannabis is scheduled.[xxvii] In August 2023, HHS recommended rescheduling cannabis to Schedule III.[xxviii] As of October 2023, the recommendation is under review within DOJ. Most of these steps will continue to be necessary regardless of scheduling (e.g., IRB approval, IND application to FDA). As suggested in a recent CRS analysis,[xxix] rescheduling has potential downstream effects within FDA and USDA, particularly in terms of increased workload and capacity of the staff and organization to absorb it.

Access to Cannabis: All the cannabis that NIDA provides is sourced from one provider, the University of Mississippi's National Center for Natural Products Research.[xxx] The products available for research are not as diverse as those in State-sanctioned retail markets (e.g., other high-potency cultivars). Clinical differences in effects of real-world products are difficult to study because these products cannot be tested by federally funded researchers. To facilitate cannabis research, NIDA's DSP provides cannabis to researchers in a range of potencies.[xxxi] The program recently gained access to seeds that will result in higher-potency bulk materials. In 2016, the DEA adopted a policy[xxxii] to facilitate research by increasing the number of entities that can cultivate and distribute research-grade cannabis. Through October 2023, the DEA has registered eight bulk growers.[xxxiii] While these additional growers may be able to provide more diverse products for research purposes, it is not yet possible to determine if such products will match those available in State-authorized dispensaries. Further, these bulk growers may not choose to participate in traffic safety related research, focusing instead on other uses such as potential therapeutic derivatives.

Ability to Conduct Side-by-Side Comparisons of Studies: Research on cannabis has the potential to influence our understanding of how it affects behavior and safety outcomes. It also has the potential to influence policy. As with any research investigation, it is important to limit and control any variability that can influence outcomes. This allows "apples to apples" comparisons of studies and builds a body of evidence on which policy can be based.

Standardization of delivery (dosing) methodology is very important to understanding research findings related to traffic safety. For example, in the type of study in which users bring their own product, as described above in Table 2, researchers do not know whether the individual consumed half a common dose, two common doses, or any other volume of THC. Common dosing protocols will harmonize interpretation of findings. Relatedly, to standardize reporting and improve comparability across research studies, in 2021, NIDA and other parts of NIH announced a 5 mg standard unit of THC for research (NOT-DA-21-049).[xxxiv] Similar standard measures have been applied for other substances. Having a standard unit of measurement for cannabis will make it easier to compare the influence of these factors on how individuals respond to the drug.

Implementing the 5 mg standard unit in research is needed to improve comparisons across studies. It will also be important to study the differential effects of a full array of cannabis and cannabinoid products, products with varying ratios of THC to CBD, and to compare the effects of different routes of administration to better understand outcomes in occasional and regular users. A standard dose also allows close examination of dose-response relationships, which will help us better understand impairing effects of cannabis.

Researcher access to funding: There is great perceived institutional risk associated with conducting research on a Schedule I substance. Because all Federal funds could be threatened by improper research, this becomes a barrier to new researchers entering the field.

Legislative uncertainty: In 2013, the Department of Justice issued *Guidance Regarding Marijuana Enforcement*, commonly referred to as the Cole Memorandum.[xxxv] Through this memorandum, the Department of Justice communicated its priorities regarding cannabis and enforcement. In 2018, the Department rescinded this memorandum, pointing to the Controlled Substances Act (21 U.S.C. § 801 et seq., and 21 U.S.C. § 841 et seq.) and the Bank Secrecy Act (18 U.S.C. §§ 1956-57, 1960; 31 U.S.C. § 5318) as indication of "Congress's determination that marijuana is a dangerous drug." The potential rescheduling of cannabis may open doors to conducting research on cannabis and driving.

Statutory and Regulatory Barriers to Establishing a National Clearinghouse for Facilitating Research on Marijuana-Impaired Driving: As noted above, NCCIH has proposed a Resource Center for Cannabis and Cannabinoid Research. The Department is not aware of any statutory or regulatory barriers to establishing this Resource Center.

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Summary

The perceived and actual barriers to conducting research on traffic safety and cannabis are surmountable. Conducting research using cannabis remains complicated by the need to protect human subjects and to prevent diversion of controlled substances. Since 2020, the DEA has enabled more licensed production of cannabis for research and has clearly delineated the steps that producers would need to take to obtain permissions.[xxxvii] NIDA's drug supply program provides easily understood information on obtaining research materials. Further, these entities provide valuable leadership in establishing the framework by which research can be used to inform policy decisions. There are opportunities to expand research on cannabis and driving, most notably via a proposed NCCIH Resource Center for Cannabis and Cannabinoid Research.

Notes

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