U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General *Washington, D.C. 20530*

SEP 16 2016

The Honorable Charles Grassley
Chairman
Caucus on International Narcotics Control
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Joseph T. Rannazzisi, former Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the Caucus on June 24, 2015, at a hearing entitled "Cannabidiol: Barriers to Scientific Research and Potential Medical Benefits." We hope that this information is of assistance to the Caucus.

Please do not hesitate to contact this office if we may be of additional assistance regarding this or any other matter. The Office of Management and Budget has advised us that there is no objection to submission of this letter from the perspective of the Administration's program.

Sincerely,

Peter J. Kadzik
Assistant Attorney General

Enclosure

cc: The Honorable Dianne Feinstein
Co-Chairman

U.S. Department of Justice
Questions for the Record
Caucus on International Narcotics Control
United States Senate
Hearing on "Cannabidiol: Barriers to Scientific Research and Potential Medical Benefits"
June 24, 2015

Questions posed by Senator Dianne Feinstein

1. **I was pleased to learn that DEA will initiate the scientific and medical evaluation of cannabidiol, commonly known as "the eight factor analysis," and look forward to the results of this evaluation.**

   a. **Has DEA already formally notified FDA of its request to initiate this evaluation? If so, on what date? If not, when do you expect to formally notify FDA?**

Response:

The Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA) have been working together to address the issues relating to cannabidiol (CBD), including scheduling recommendations. The scheduling determinations must undergo a scientific and deliberate interagency process. NIDA and FDA have been working to complete an extensive literature review of human and animal studies that have evaluated CBD in terms of its abuse potential, pharmacology chemistry, adverse effects, and dependence. In carrying out scheduling activities related to CBD, DEA and FDA will follow the procedures set forth in 21 U.S.C. § 811 and § 812.

   b. **When does DEA expect to complete its portion of the eight factor analysis?**

Response:

As indicated in response to Question 1a, above, DEA will make a formal request to the Department of Health and Human Services (HHS)/FDA once the initial data collection and analysis is complete. The time frame for DEA to complete its data collection and review depends upon the amount of data available on the substance. There is a substantial amount of scientific data on CBD. In the meanwhile, DEA is working diligently to complete its data collection and analysis as soon as possible.

   c. **If the evaluation finds that cannabidiol should be rescheduled or decontrolled, what impact would that have on the schedule of marijuana, if any, given that cannabidiol is derived from marijuana?**

Response:

Scheduling actions are substance-specific. Any scheduling action pertaining to CBD would be unique to CBD, and would not have an impact on the control status of marijuana under the Controlled Substances Act (CSA).

2. **DEA stated that it has recently expanded the total number of Schedule I research licenses to nearly 400 and that it is expediting applications for research on cannabidiol.**

    a. **If marijuana or cannabidiol were moved to Schedule II, approximately how many DEA licensees would be authorized to conduct research without needing an additional license, as currently required for Schedule I research?**

Response:

The CSA does not require a separate researcher registration if a registered practitioner desires to conduct research involving a schedule II-V controlled substance. 21 U.S.C. § 823(f). The only federal CSA requirement is that the practitioner have authority as a practitioner to handle the particular schedule to be researched (e.g., the practitioner must have authority to handle schedule II controlled substances in order to research schedule II controlled substances). As of February 8, 2016, there were more than 933,000 active medical doctors and osteopathic doctors registered with the DEA to handle schedule II controlled substances.

However, please be aware that bona fide researchers are required to have sound scientific study designs and protocols to conduct research. Often the research design and protocol must be reviewed and approved by the researcher's institution prior to conducting research, i.e. an institutional review board or "IRB." Therefore, the number of DEA registrants authorized to conduct research without an additional researcher registration is highly dependent on which researchers are conducting bona fide research.

3. **In your testimony, you noted that DEA will continue to work with the Department of Health and Human Services to streamline the Schedule I researcher registration process and identify new opportunities for improvement.**

    a. **In addition to expediting the DEA registrations to conduct research on Schedule I substances, has DEA identified any new opportunities for improvement or additional regulations to streamline? Please explain.**

Response:

DEA is in the process of drafting a researcher manual to explain all aspects of the application process for schedule I researcher registration. DEA hopes that providing a single source for all relevant information will increase understanding of the pertinent requirements and streamline the registration process for researchers. DEA will make this manual available to the public by

posting it on the DEA website. DEA also plans to implement changes to the application process by giving researchers the option to apply for a schedule I researcher registration online.

Recently, the DEA announced a policy change designed to foster research by expanding the number of DEA-registered marijuana manufacturers.[1] This policy change should provide researchers with a more varied and robust supply of marijuana. At present, there is only one entity authorized to produce marijuana to supply researchers in the United States: the University of Mississippi, operating under a contract with NIDA. Consistent with the CSA and U.S. treaty obligations, DEA's new policy will allow additional entities to apply to become registered with DEA so that they may grow and distribute marijuana for FDA-authorized research purposes.

In addition, relevant federal agencies, including the Office of National Drug Control Policy (ONDCP), NIDA, FDA, and DEA, have convened an interagency working group to review additional actions that may be taken to encourage bona fide marijuana research.

4. I would like to better understand the potential benefits of placing drugs in Schedule II of the Controlled Substances Act.

a. Outside of reducing barriers to research, if marijuana or cannabidiol were moved to Schedule II, would there be any immediate benefits, or would any potential benefits be contingent on an FDA-approved formulation?

Response:

By definition under the CSA, schedule II controlled substances have "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." 21 U.S.C. § 812(b)(2)(B). Simply placing a substance in schedule II would not allow the substance to be lawfully prescribed, rather, the substance must be approved under the Federal Food Drug and Cosmetic Act (FDCA) to be a drug used in medical treatment. We would respectfully refer you to HHS/FDA regarding the requirements governing clinical indications for medical use (medical benefits) of such substances and any questions regarding FDA-approved formulations to the FDA.

b. Would medical marijuana patients be able to legally cross state lines with cannabidiol in their possession if it were Schedule II?

[1] Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States: https://www.federalregister.gov/articles/2016/08/12/2016-17955/applications-to-become-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to?utm_campaign=pi+subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov.

Response:

Under the CSA, it is "unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized . . . ." 21 U.S.C. § 844(a). Validly prescribed and lawfully dispensed schedule II controlled substances become the property of the ultimate user and are outside the closed system of distribution established by the CSA.

5. **Both FDA and NIDA stated that additional marijuana cultivation sites would be beneficial for marijuana and cannabidiol research.**

   a. **Does DEA believe it has the existing authority to authorize additional marijuana cultivation sites and will it take steps to do so?**

Response:

Recently, the DEA announced a policy change designed to foster research by expanding the number of DEA-registered marijuana manufacturers.[2] This policy change should provide researchers with a more varied and robust supply of marijuana. At present, there is only one entity authorized to produce marijuana to supply researchers in the United States: the University of Mississippi, operating under a contract with NIDA. Consistent with the CSA and U.S. treaty obligations, DEA's new policy will allow additional entities to apply to become registered with DEA so that they may grow and distribute marijuana for FDA-authorized research purposes.

   b. **The United Kingdom has licensed pharmaceutical companies to grow medical marijuana without violating its U.N. treaty obligations. Why could the United States not do the same?**

Response:

DEA does not have sufficient information regarding the cultivation of cannabis in the United Kingdom on which to base an opinion as to whether such activity is in compliance with international treaty obligations.

[2] Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States: https://www.federalregister.gov/articles/2016/08/12/2016-17955/applications-to-become-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to?utm_campaign=pi+subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov.

Questions posed by Senator Jeff Sessions

6. **A great deal has been made of anecdotal accounts of cannabidiol (CBD) oil ameliorating the symptoms of various types of epilepsy.**

   a. **What clinical or medical research-based evidence is there that the CBD oils used in these accounts are in fact, CBD oil?**

Response:

DEA has not yet concluded its collection, review, and analysis of the available data on CBD. Use of any CBD oil not subject to an HHS/FDA approved Investigational New Drug application (IND) is unlawful under the CSA. We would respectfully refer you to HHS, which may have information in response to this question as this type of clinical research is within HHS jurisdiction.

   b. **Are the specific or dedicated laboratories that supposedly test the content of these oils regulated by FDA? If the answer is yes, please provide additional information about these laboratories, including explanation of how DEA certifies these laboratories.**

Response:

Only DEA registered laboratories may lawfully accept and analyze controlled substances. To register these laboratories, DEA would ensure these laboratories meet the CSA requirements prior to issuing a registration to conduct analysis. The relevant factors considered for registration are outlined in 21 U.S.C. §§ 823(f) and 824(a). DEA defers to HHS regarding its regulation of these laboratories.

   c. **Is there a difference between the oils that have been used to support these anecdotal accounts and the CBD oil currently being tested by the FDA? If the answer is yes, please provide additional information.**

Response:

DEA would respectfully refer you to HHS regarding any testing it may be conducting on CBD oil.

7. **In April 2013, DEA released a report entitled "The DEA Position on Marijuana." The report, in addition to restating that marijuana, regardless of form, continues to be classified as a Schedule I controlled substance under the Controlled Substances Act (CSA), emphasizes that smoked marijuana is not medicine, and lists major U.S.-based medical associations that have rejected the viewpoint that smoked marijuana is medicine, including the American Medical Association, the American Society of Addiction Medicine, the American Cancer Society, the American Glaucoma Society, the**

Glaucoma Research Foundation, the American Academy of Pediatrics, the American Academy of Child and Adolescent Psychiatry, and the National Multiple Sclerosis Society. The opposition of these associations to the idea that smoked marijuana is medicine is notable, not only because of the renown of these associations, but also because many cover the illnesses that are supposedly eased by marijuana.

a. Have any of the above-listed associations reversed or in any way adjusted their views regarding the non-medicinal quality of smoked marijuana? If the answer is yes, please provide additional information.

Response:

DEA would respectfully refer you to the American Academy of Pediatrics' January 2015 opinion in response to this question. Similarly, DEA would refer you to the National Multiple Sclerosis Society 2015 positional stance.

b. Are any of these associations in the process of re-evaluating their positions with respect to smoked marijuana?

Response:

DEA would respectfully refer you to these associations for additional information regarding whether they are internally re-evaluating their positions on smoked marijuana.

c. Does the fact that smoking marijuana causes a "high" mean that marijuana is "medicinal" or can be considered "medicine"?

Response:

The "high" is an indication of the drug's psychotropic effect, not an indication of its use as a medicine.

8. Can you describe the qualitative differences between cannabis grown for a high THC content, cannabis grown for a high CBD content, and cannabis grown for other purposes?

Response:

Pursuant to the CSA, marijuana grown for a high tetrahydrocannabinol (THC) content, high CBD content, or grown for other purposes would all be considered the same qualitatively and would be schedule I substances. Hemp, which is cannabis containing 0.3% or less THC, would be the only form of cannabis that would be considered qualitatively different according to federal law.

9. **A bill has been introduced in the Senate that would de-schedule CBD and define a "CBD-rich plant" as any part of a cannabis plant that contains less than 0.3 percent THC.**

   a. **From an enforcement standpoint, how would a DEA agent be able to quickly and efficiently tell what percentage of THC a cannabis plant contained?**

Response:

The only way to determine the percentage of THC a cannabis plant contains is through laboratory testing; the THC percentage cannot be determined by merely looking at a plant without further testing. Presumptive field tests conducted by law enforcement personnel on suspected substances only reveal the presence of a controlled substance. This presumptive field test does not provide a quantitative or qualitative value of the controlled substance.

   b. ***Looking at a cannabis field, how could an agent quickly determine whether the plants are "CBD-rich plants" under the definition above and not marijuana plants?***

Response:

It is not possible for any person to determine if a plant is "CBD-rich." The plants would have to be sent for laboratory analysis for quantitative and qualitative testing. It is important to also note that a plant must be mature in order to determine the true level of THC.

10. **By all accounts, the legalization of marijuana in Colorado has been a disaster. In a February 2015 article entitled "Year One of Colorado's Marijuana Law," former director of the Office of National Drug Control Policy (ONDCP) under President George W. Bush, John Walters, and former ONDCP chief scientist, David Murray, wrote:**

> **Arrests for illegal (mostly underage) use increased in Denver 260 percent during 2014, even before the year ended. Hospital emergency departments experienced an increase in marijuana-related episodes, including severe burns from butane explosions as users concentrated THC, the intoxicating chemical.**
>
> **Schools report disciplinary problems, often from youth using 'vaporizers' in class. Daily use of the drug, highly damaging, is soaring, with Colorado already exhibiting rates 35 percent higher than the national average. Law enforcement reports a continuing black market, in part because of taxes on the official product.**
>
> **Is marijuana crossing state lines? Colorado marijuana is affecting 40 additional states, according to the same law enforcement report stating, 'By legalizing marijuana … instead of eliminating (the black market), we have become it.' The problem is so severe that Nebraska and Oklahoma will sue, arguing that Colorado**

has 'created a dangerous gap' in the federal drug-control system, where 'Marijuana flows from this gap into neighboring states.'

These documented violations of the supposed 'red lines' set by DOJ have simply been ignored. Increased drug use, measured even before commercial sales, can be seen in state-level data from the National Survey on Drug Use and Health, where mere anticipation of the law shaped increases. Comparing the period 2011-2012 against 2012-2013, of Coloradans 12 and older, there was a 22 percent increase in regular marijuana use and a 33 percent increase for those 26 and older. There will be worse to come.

The acceptance of marijuana use was clear in the youth study Monitoring the Future (MTF), which reported a sharp decrease nationwide in perceptions of risk in smoking marijuana in 2014, a decline since 2009 of 31 percent among 12th graders. Historically such declines presage a surge in adolescent use—indicating we are likely in the calm before a coming storm.

Many 2014 news accounts stressed how 'successful' the law has been despite the absence of 2014 data. In one sense, the Colorado experiment has worked; marijuana is widely consumed by Colorado residents (including homeless arrivals) and drug tourists (the Department of Revenue reported 45 percent of sales to out-of-state ID holders), while potency has skyrocketed.

There is additional impact on laws such as child endangerment and food safety. Nationwide, Monitoring the Future reports 26 percent of 12th graders who used marijuana in the past year have consumed edibles laced with the intoxicant THC. 'Legal' marijuana edibles are reported to be nearly half of all commercial sales in Colorado.

Further, to facilitate the Colorado market, banking rules against criminal enterprises are being dismantled by DOJ guidance, while marijuana businesses are insulating themselves against state regulation. State coffers have not realized the projected benefits from taxes, while the payment of federal taxes is a mystery, since the business remains illegal at the federal level. The threat to public integrity is real.

a. **Please describe the challenges DEA faces as a result of marijuana legalization for recreational use in Colorado.**

Response:

DEA shares your concerns about the dangers to public health and safety posed by large-scale drug traffickers and we remain committed to enforcing the CSA. In enacting the CSA, Congress determined that marijuana is a dangerous drug and that the illegal distribution and sale of marijuana is a serious crime that provides a significant source of revenue to large-scale criminal

enterprises, gangs, and cartels. DEA is committed to the enforcement of the CSA consistent with those determinations.

On August 29, 2013, then-Deputy Attorney General James M. Cole issued guidance to all U.S. Attorneys' Offices regarding marijuana enforcement (August 29th memorandum). This memorandum provides all U.S. Attorneys with guidance regarding federal enforcement in all states, including those states that have legalized marijuana. As laid out in the August 29th memorandum, the Department of Justice (the Department) and DEA will continue to focus resources on the most significant public health and safety threats to our communities.

Colorado's marijuana laws have resulted in a significant and growing production industry. The legalization of recreational marijuana has increased the level of marijuana production in the state as a result of both Amendment 20 (medical use of marijuana) and Amendment 64 (use and regulation of marijuana for non-therapeutic use) to Colorado state law. One concern DEA has is regarding drug trafficking under the guise of the state's licensed industry. One of the eight enforcement priorities in the August 29th memorandum is preventing the interstate distribution of marijuana from states where it is legal in some form to states where it is not. The Department and DEA continue to work closely with state and local authorities to enforce the law in this important area as close federal, state, and local cooperation is essential to ensure effective enforcement.

Another particularly disconcerting trend DEA is seeing in Colorado is the issue of edible marijuana products and the possibility of these products falling into the hands of children. Edibles potentially implicate at least two of the eight priorities identified in the August 29th memorandum, namely, preventing (1) the distribution of marijuana to minors, and (2) the exacerbation of adverse public health consequences associated with marijuana use. DEA will not hesitate to investigate individuals and businesses whose conduct involves distribution to minors or poses serious public health risks due to the dangers associated with consumption – accidental or intentional – by minors.

b. Please describe the trends in drug usage that DEA has seen since marijuana was legalized for recreational use in Colorado.

Response:

Prevalence, patterns, and consequences of illegal drug use in the United States are studied by HHS, specifically the Substance Abuse and Mental Health Services Administration (SAMHSA). Accordingly, we would respectfully refer you to their website for the latest results from the National Survey on Drug Use and Health (NSDUH), located at http://www.samhsa.gov/data/population-data-nsduh.

c. Please describe the trends in criminal activity, including with respect to drug trafficking, that has DEA seen since legalization took effect in Colorado.

Response:

Since Colorado legalized marijuana, DEA has observed an influx of both individuals and organized groups of individuals who have relocated to Colorado for the sole purpose of producing marijuana to transport and sell in other markets. Many of these operations involve multiple homes that are purchased or rented and converted into grow sites. Investigations have revealed that many of these individuals are armed.

DEA, along with other federal, state, and local partners, has taken a lead role in addressing the illegal cultivation of marijuana in Colorado. For example, in the fall of 2015, 32 individuals were arrested and face federal drug trafficking charges brought by the U.S. Attorney's Office in Denver, Colorado. *See*, https://www.justice.gov/usao-co/pr/confronting-wave-illicit-marijuana-cultivation-federal-state-and-local-authorities.

d. Please describe how Colorado's legalization of marijuana for recreational use has impacted the federal, state, local, and tribal law enforcement efforts in the states that surround Colorado.

Response:

Based on our ongoing liaison efforts with our state and local law enforcement counterparts throughout the Midwest and East Coast, we have learned that individuals are transporting large loads of Colorado-produced marijuana across state lines and into their jurisdictions. Of the 394 seizures in 2015, there were 36 different states destined to receive marijuana from Colorado.[3]

DEA's investigations reveal that the financial system may also be exploited by marijuana traffickers based in Colorado. Most recently, DEA has identified the widespread use of funnel accounts. Cash from marijuana purchases are deposited into the sources' bank accounts at branches throughout the midwestern and eastern United States. Within a day or two, the money is withdrawn at ATMs in Colorado or transferred to additional accounts, often affiliated with marijuana-related businesses. Reporting by banks document millions of dollars in cash deposits related to out-of-state marijuana sales in recent months.

11. In his 2013 memorandum to U.S. Attorneys regarding the Obama administration's position on enforcement of federal marijuana laws in states where it is legalized, then-Deputy Attorney General James Cole wrote that the Justice Department would not enforce the Controlled Substances Act, but rather would focus on the following priorities:

- **Preventing the distribution of marijuana to minors;**
- **Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;**

[3] http://www.rmhidta.org/html/2016%20FINAL%20Legalization%20of%20Marijuana%20in%20Colorado%20The%20Impact.pdf.

- **Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;**
- **Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;**
- **Preventing violence and the use of firearms in the cultivation and distribution of marijuana;**
- **Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;**
- **Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and**
- **Preventing marijuana possession or use on federal property.**

a. Please describe what the Justice Department is doing to monitor the eight "federal" priorities set forth in the aforementioned "Cole Memorandum."

Response:

The Department is monitoring the effects of state marijuana legalization relative to the Department policy, generally in two ways. First, U.S. Attorneys prosecute cases that threaten federal marijuana enforcement priorities and consult with state officials about areas of federal concern, such as the potential impact on enforcement priorities of edible marijuana products. Second, there is collaboration within the Department and its components, including DEA, and with other federal agencies, including ONDCP, as they assess various marijuana enforcement-related data these agencies provide.

The Department is committed to creating and instituting a monitoring plan to document available information about the effects of the legalization of marijuana in the states. The Office of the Deputy Attorney General has asked the Executive Office for the United States Attorneys (EOUSA), working with the Attorney General's Advisory Committee (AGAC) and the Narcotics and Dangerous Drug Section of the Criminal Division, to develop a repository of data and assessments of state marijuana legalization efforts, particularly focusing on data and assessments that may provide information relevant to the Department's stated federal enforcement priorities. This repository providing data concerning the effects of state marijuana legalization will help inform the judgments made by the Department as it makes resource and enforcement decisions with regard to marijuana and related criminal and civil enforcement actions.

In identifying and compiling this data, the Department will identify sources of information from within the Department, specifically including the DEA, the Organized Crime Drug Enforcement Task Forces, the U.S. Attorneys' Offices, and the Office of Justice Programs, as well as from other federal sources, including ONDCP and HHS, and from state and local law enforcement and public health organizations.

Recognizing that, due to the evolving nature of this issue, new and additional sources of data will arise over time, the Department will seek to maintain and update this repository regularly so that the information contained therein is comprehensive and timely. Additionally, the Department

will seek to publish on a publicly-accessible Department website such information that is available to the public. Discussions are currently under way within the Department to determine how this effort will be staffed.

b. Does federal law currently proscribe the sale or use of marijuana for supposedly medical purposes?

Response:

Marijuana currently has no accepted medical use and is therefore by definition a schedule I controlled substance under federal law. For this reason, human consumption of marijuana is prohibited, except in a research setting where the researcher is registered with DEA and the research is carried out in conformity with the FDCA. Marijuana is also an unapproved drug under the FDCA because it has never been demonstrated that it can be used safely and effectively for the treatment of any disease or condition. Accordingly, the introduction of marijuana into interstate commerce for use as a drug is unlawful under the FDCA.

c. Does federal law currently proscribe the sale or use of marijuana for recreational purposes?

Response:

Federal law currently proscribes the sale or use of marijuana for recreational purposes. Based on the legal standards in the CSA, marijuana remains a schedule I controlled substance because it does not meet the criteria for currently accepted medical use in treatment in the United States, there is a lack of accepted safety for its use under medical supervision, and it has a high potential for abuse.

d. Given that the Cole Memorandum essentially instructs federal law enforcement and prosecutors not to enforce current federal drug laws, could it be argued that the Cole Memorandum actually prevents the use of prosecutorial discretion in marijuana-related criminal cases?

Response:

The August 29th Cole Memorandum directs prosecutors and agents to continue to investigate and prosecute marijuana cases on a case-by-case basis, and the primary question in all cases will be whether the conduct at issue implicates one or more of the federal enforcement priorities set forth in that memorandum. In many cases, the conduct of individuals operating outside the scope of state marijuana laws will also harm those federal enforcement priorities. In those cases where the conduct does not harm federal priorities, we expect our state and local partners to address those cases consistent with the traditional federal-state approach to drug enforcement.

e. Have any DEA agents or, to your knowledge, any U.S. Attorneys' Offices, been disciplined by the Justice Department for pursuing marijuana-related criminal cases? If so, please provide relevant documents and/or information, including

information about the personnel involved and the timing and circumstances of discipline.

Response:

There is no information that DEA Agents have been disciplined by the Department for pursuing marijuana-related cases.

12. Please describe the challenges that DEA faces with respect to states that have legalized marijuana for supposedly medicinal purposes.

a. Please describe the trends in drug usage that DEA has seen since marijuana was legalized for supposedly medicinal purposes in these states.

Response:

Prevalence, patterns, and consequences of illegal drug use in the United States are studied by HHS, specifically SAMHSA. Accordingly, we would refer you to their website for the latest results from the NSDUH, located at http://www.samhsa.gov/data/population-data-nsduh.

b. Please describe the trends in criminal activity, including with respect to drug trafficking, that has DEA seen since marijuana was legalized for supposedly medicinal purposes in these states.

Response:

Individuals and organized criminal organizations are capitalizing on state initiatives that recognize marijuana as medicine. State regulations pertaining to medical marijuana programs vary significantly; therefore each has different trends in criminal activity. Some states appear to have highly regulated medical marijuana programs while other states' regulatory programs are not well-defined or enforced.

Trends include, but are not limited to:

- Diversion of marijuana cultivated by individuals with marijuana recommendations.
- Diversion of marijuana purchased at marijuana dispensaries by individuals with marijuana recommendations.
- Purchasing marijuana without a marijuana recommendation.
- Organized groups obtaining multiple marijuana recommendations to grow large amounts of marijuana with intent to sell it for profit both in and out of the state.
- Robberies at marijuana dispensaries.
- Robberies at personal/residential marijuana grows.
- Theft of electricity to operate marijuana grows.
- Individuals and criminal organizations cultivating marijuana without recommendations.

c. Please describe how these states' legalization of marijuana for supposedly medicinal use has impacted the federal, state, local, and tribal law enforcement efforts in the states that surround these states.

Response:

DEA focuses its limited resources on the major drug trafficking organizations that are producing and distributing illicit drugs. The August 29th Cole Memorandum directs prosecutors and agents to continue to investigate and prosecute marijuana cases on a case-by-case basis, and the primary question in all cases will be whether the conduct at issue implicates one or more of the federal enforcement priorities set forth in that memorandum. In many cases, the conduct of individuals operating outside the scope of state marijuana laws will also harm those federal enforcement priorities.

d. Is it reasonable to say that laws that permit the unchallenged availability of marijuana (for either supposedly medicinal or recreational purposes) create an environment that essentially provides a "cover" for drug trafficking organizations to sell their illegal marijuana in the U.S.?

Response:

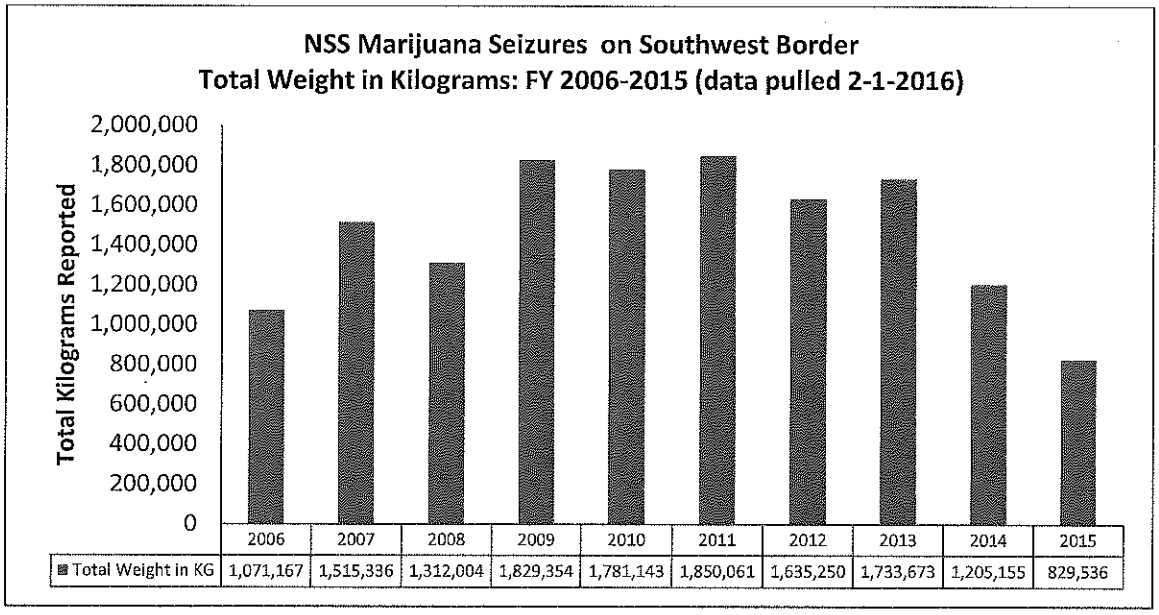
The cultivation of marijuana under the auspices of state law has created unique challenges for state and local law enforcement. Some of these challenges are outlined below.

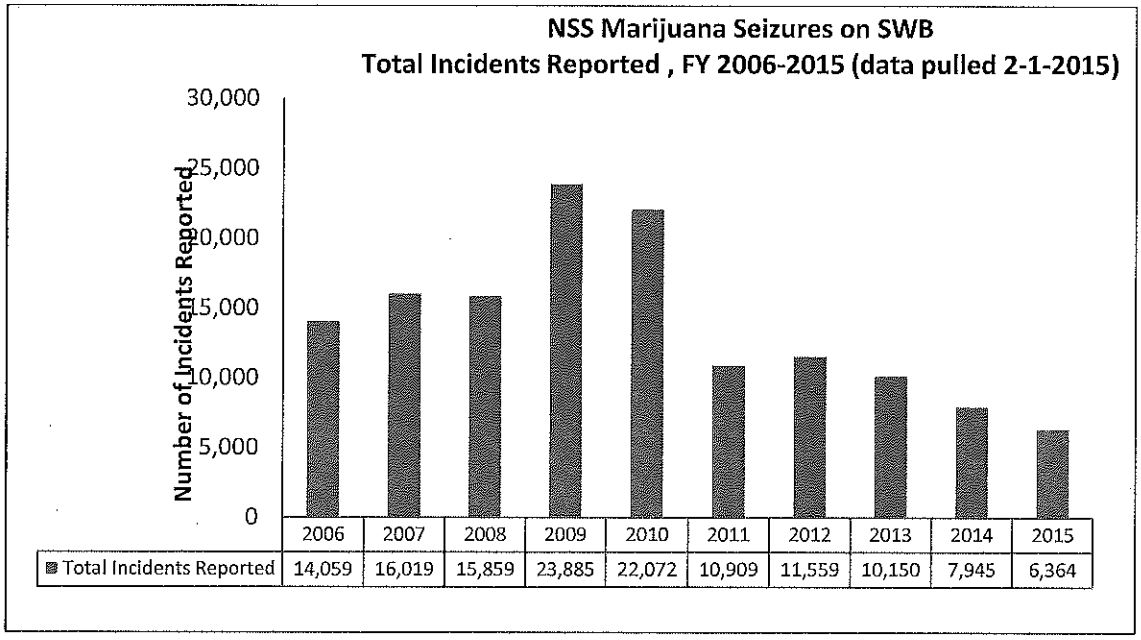
- State-approved recreational and medical marijuana can be diverted illegally for profit.
    - For example, someone from Colorado with a medical marijuana recommendation for 75 plants and 25 ounces can easily exploit the state-approved medical system. This person can grow 75 plants and purchase 25 ounces (1.5 pounds) daily and sell the marijuana for a profit.
    - A medical marijuana recommendation in Washington is capped at 15 plants, but there is no state registry requirement at this time, which has allowed trafficking organizations to create fake doctors recommendations as a potential cover.
    - California does not track medical marijuana patients like Colorado and no registry card is needed to purchase or grow marijuana. This has created an environment where many criminal organizations obtain sham medical recommendations as a cover for profiting from growing marijuana.
- Small-scale and large-scale drug trafficking organizations are able to operate under the guise of legality with more ease than in the past. Many of the states have approved personal marijuana grows for recreational or medical purposes.

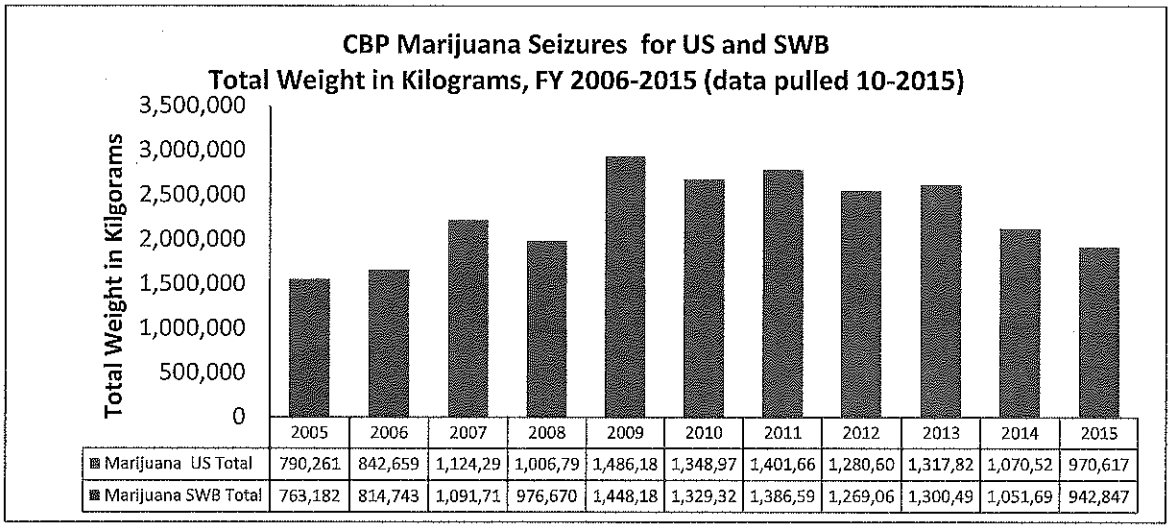
e. Please provide up-to-date information about the seizures of marijuana at the U.S.-Mexico border for FY 2006-2015 (for FY 2015, as of June 30, 2015).

Response:

Marijuana seizures have declined since 2013 along the U.S. – Mexico border as indicated by both National Seizure System data and U.S. Customs and Border Protection (CBP) data.







	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Marijuana US Total	790,261	842,659	1,124,29	1,006,79	1,486,18	1,348,97	1,401,66	1,280,60	1,317,82	1,070,52	970,617
Marijuana SWB Total	763,182	814,743	1,091,71	976,670	1,448,18	1,329,32	1,386,59	1,269,06	1,300,49	1,051,69	942,847

13. What are the criteria for a Schedule II drug under the Controlled Substances Act?

Response:

Pursuant to 21 U.S.C. § 812(b)(2), the findings required for schedule II drugs are as follows: the drug or other substance has a high potential for abuse; the drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and, abuse of the drug or other substances may lead to severe psychological or physical dependence.

It is important to note that both schedule I and schedule II controlled substances have a "high potential for abuse." 21 U.S.C. §§ 812(b)(1)(A) and (b)(2)(A). What distinguishes substances in schedule II from those in schedule I is that the former have an accepted medical use and the latter do not. To be placed in schedule II, a controlled substance must have "currently accepted medical use in treatment in the United States" or a "currently accepted medical use with severe restrictions." 21 U.S.C. § 812(b)(2)(B). In either case, to be placed in schedule II, the controlled substance must have a "currently accepted medical use," which must be predicated on one of the following two of criteria: (i) the drug has been approved for marketing by the FDA or (ii) the drug satisfies a five-part test for determining currently accepted medical use in the absence of FDA-approval. Under the latter criterion, the five-part test consists of the following:

(1) The drug's chemistry must be known and reproducible;
(2) There must be adequate safety studies;
(3) There must be adequate and well-controlled studies proving efficacy;
(4) The drug must be accepted by qualified experts; and
(5) The scientific evidence must be widely available.

57 Fed. Reg. 10499, 10504-10506 (1992). Failure to meet any of these five prongs precludes a finding that the drug has a currently accepted medical use in treatment in the United States for purposes of the CSA. *Id.*; *see also Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131,

1135 (D.C. Cir. 1994); *Americans for Safe Access v. DEA*, 706 F.3d 438, 449-450 (D.C. Cir. 2013).

a. Does marijuana currently meet Schedule II criteria?

Response:

On August 11, 2016, the DEA published responses to two pending petitions to reschedule marijuana.[4] DEA has denied these two petitions under the CSA. In response to the petitions, DEA requested a scientific and medical evaluation and scheduling recommendation HHS, which was conducted by the FDA in consultation with NIDA. Based on the legal standards in the CSA, marijuana remains a schedule I controlled substance because it does not meet the criteria for currently accepted medical use in treatment in the United States, there is a lack of accepted safety for its use under medical supervision, and it has a high potential for abuse. In a letter dated August 11, 2016, DEA Acting Administrator Chuck Rosenberg offered a detailed response outlining the factual and legal basis for the denial of the petitions. The full responses to the petitions can be found online in the Federal Register.[5]

b. Is marijuana currently available for medical research in the United States? If the answer is yes, please provide a detailed explanation about how a research institution or organization can obtain and use marijuana for research purposes.

Response:

Yes, marijuana is currently available for research in the United States. Consistent with the obligations of the United States under the Single Convention on Narcotic Drugs, 1961, the U.S. Government controls the distribution of marijuana to researchers, acting through NIDA. DEA defers to NIDA as to the specific details of how NIDA provides marijuana to researchers, but we note that NIDA has published information on this subject on its website at www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research.

In addition, DEA recently announced a policy change designed to foster research by expanding the number of DEA-registered marijuana manufacturers.[6] This policy change should provide researchers with a more varied and robust supply of marijuana. As stated above, at present, there is only one entity authorized to produce marijuana to supply researchers in the United States: the University of Mississippi, operating under a contract with NIDA. Consistent with the CSA and

[4] DEA Announces Actions Related to Marijuana and Industrial Hemp: https://www.dea.gov/divisions/hq/2016/hq081116.shtml.

[5] Denial of Petition to Initiate Proceedings to Reschedule Marijuana: https://www.federalregister.gov/articles/2016/08/12/2016-17954/denial-of-petition-to-initiate-proceedings-to-reschedule-marijuana?utm_campaign=pi+subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov.

[6] Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States: https://www.federalregister.gov/articles/2016/08/12/2016-17955/applications-to-become-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to?utm_campaign=pi+subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov.

U.S. treaty obligations, DEA's new policy will allow additional entities to apply to become registered with DEA so that they may grow and distribute marijuana for FDA-authorized research purposes.

c. Is it reasonable to say that institutions or organizations that have complained about the lack of access to marijuana for research purposes have simply had trouble demonstrating that their studies meet acceptable standards for research or otherwise have failed to demonstrate eligibility for receipt of the marijuana? If possible, please provide concrete examples of institutions or organizations that have been rejected for receipt of marijuana for research purposes, with details about the bases for rejection.

Response:

The CSA allows for research to be conducted with marijuana (or any other schedule I controlled substance) where HHS has determined that the research protocol is scientifically meritorious and the researcher is qualified. 21 U.S.C. § 823(f). In addition, in accordance with the FDCA, to protect the safety of the human research subjects, the research must be conducted pursuant to a valid Investigational New Drug (IND) application reviewed by the FDA. 21 U.S.C. § 355(i). In every instance where HHS has determined a marijuana research proposal to be scientifically meritorious, DEA has issued a registration authorizing the research under the CSA. There have been a few instances in which marijuana research protocols were found by HHS to be lacking in scientific merit and, for this reason, marijuana was not provided by NIDA to the researcher. However, DEA is unaware of any instance in which a scientifically sound marijuana research proposal was denied access to marijuana by the federal government. A detailed assessment of this subject, including concrete examples of entities that applied for marijuana from NIDA, is contained in a document published by DEA in the Federal Register. 76 Fed. Reg. 51403, 51405-51409 (2011), *pet. for review denied, Craker v. DEA*, 714 F.3d 17 (1st Cir. 2013).

d. Would rescheduling marijuana implicate the United States' obligations under the Single Convention on Narcotic Drugs – a treaty signed and ratified by the U.S. in 1961? If so, how?

Response:

Depending on the basis for doing so, the rescheduling of marijuana could implicate U.S. obligations under the Single Convention. If the U.S. Government were to simply declare – in the absence of a determination by the FDA to this effect– that marijuana has a currently accepted medical use and should be removed from schedule I, this would contravene U.S. obligations under the Single Convention. The International Narcotics Control Board (INCB) is the component of the United Nations charged with monitoring compliance with the Single Convention and other drug control treaties. The INCB has stated: "The decision of whether a substance should be authorized for medical use has always been taken, and should continue to be taken, in all countries by the bodies designated to regulate and register medicines. [In the United States, these bodies are the FDA and DEA.] Such decisions should have a sound medical and scientific basis and should not be made in accordance with referendums organized by interest

groups."[7]

There are numerous control measures that the United States must apply to marijuana in order to meet the country's obligations under the Single Convention. Some of these control measures are discussed in the answer to the next question. If the Government were to remove marijuana from schedule I and place it in a different schedule, the United States would still be obligated to maintain the controls measures applicable to cannabis set forth in the Single Convention.

e. Specifically, how does the Single Convention on Narcotic Drugs impact the DEA's regulation of marijuana for research purposes?

Response:

Under the Single Convention, the United States is obligated to ensure that only licensed (DEA-registered) growers produce the marijuana that is used for research and that only DEA-registered researchers carry out clinical trials involving marijuana. In addition, the Single Convention requires, with respect to cannabis (and other drugs covered by the treaty) that the United States establish annual manufacturing quotas for the country as a whole and for individual manufacturers, which DEA establishes quantities sufficient to meet legitimate research needs of the United States.

[7] Report of the INCB for 1998, par. 259. Available at www.incb.org/documents/Publications/AnnualReports/AR1998/AR_1998_E.pdf.