Nominations Hearing

November 13, 2014

Questions for the Record from Senator Dianne Feinstein

for

Michael Botticelli, Acting Director, Office of National Drug Control Policy

1. As you know, despite Congressional action two years ago that outlawed several synthetic drugs, manufacturers and distributors have managed to stay one step ahead of the law by slightly altering the chemical structures that produce "controlled substance analogues," which mimic the psychoactive effects of drugs like ecstasy, cocaine, PCP, and LSD. These slight changes have enabled manufacturers and distributors to avoid prosecution and have led to overdoses and deaths, primarily amongst our nation's youth.

    - *My staff has repeatedly heard from the Drug Enforcement Administration, Department of Homeland Security and others that a more efficient, permanent scheduling process is crucial to staying ahead of synthetic drug manufacturers. In your view, would legislation that enables synthetic substances to be scheduled more expeditiously help address the import, manufacture, and distribution of these dangerous synthetic drugs?*

ANSWER: While the existing procedure to control substances is sufficient with respect to known substances (e.g., chemical entities approved for medical use), legislation that enables new psychoactive substances to be permanently controlled quickly would help address the import, manufacture, and distribution of these dangerous drugs. Currently, the Controlled Substances Act (CSA) requires the Drug Enforcement Administration to wait for the next new psychoactive substance to be synthesized, identified, and sold in retail environments with labeling designed to circumvent the Analogue Act. As a result, individuals who abuse substances and unsuspecting youth have been exposed to dangerous substances and, in many instances, have even suffered adverse health consequences, including death. We would be happy to work with your office on legislation to address this concern.

2. In 2012, Colorado and Washington legalized the production, distribution, possession, and use of marijuana for recreational purposes. Recently, Oregon and Alaska approved similar initiatives, while the District of Columbia approved the possession, use, and production of marijuana.

    - *Does ONDCP believe that these laws are in conflict with the United States' obligations under the U.N. Conventions, which require state parties to limit the production, distribution, possession, and use of marijuana to scientific and medical purposes?*

ANSWER: We respect the democratic process, but the evidence pointing to serious health risks associated with cannabis use, particularly by children and young adults, remains unchanged. This is why the Office of National Drug Control Policy (ONDCP) is spearheading an effort by the Federal Government to monitor cannabis use in the United States so that we may scientifically examine its effects. We believe that the policies set forth in the U.N. drug conventions limiting access to controlled substances for medical and scientific purposes are sound, and based on valid health concerns. The United States is firmly committed to upholding our obligations under the three U.N. drug conventions, as well as working with international partners to promote the goals of those conventions. These conventions are the foundation of international cooperation for dealing with all aspects of the drug problem, and we support them unwaveringly.

Under U.S. Federal law, marijuana remains a Schedule I drug under the CSA, subject to a high level of control, with criminal penalties for its illegal distribution and sale.

The Federal Government is committed to enforcement of the CSA. The Department of Justice (DOJ) articulated eight Federal enforcement priorities with respect to cannabis (see Memorandum from Deputy Attorney General Cole dated August 29, 2013) and is currently investigating and has prosecuted criminal enterprises involved in marijuana trafficking and violence in all areas of the country. Additionally, ONDCP and its Federal partners are monitoring the implementation of state-level initiatives.

While the consequences of legalization measures in four states are a serious concern, U.S. compliance with the Conventions has not changed.

- *The State Department recently called for a flexible interpretation of the U.N. Conventions. Does ONDCP support a flexible interpretation of the U.N. Conventions? If so, what does ONDCP's interpretation look like?*

ANSWER: The U.S. Government strongly supports the U.N. drug control conventions that have been the foundation of global anti-drug efforts since the initial opium convention in 1912. The three modern conventions (1961, 1971, and 1988) continue to serve as the essential guiding documents to help all governments forge strong and effective drug policies. The United States opposes efforts to alter the Conventions.

Per the requirements of the Conventions, as well as our domestic laws, the U.S. Government heavily emphasizes proactive enforcement of laws against drug production and trafficking, as well as related money laundering, violence, and other illegal activities that impact the safety of our citizens. We lead the world in efforts against international drug cartels wherever they operate, and have – with the strong support of the Congress over many years – provided training, technical assistance, and other aid to key partners around the world, especially in the Western Hemisphere to help them disrupt and dismantle these organizations.

ONDCP supports what the Department of State has termed a "flexible" interpretation of the conventions, which addresses the range of responses to drug problems that the conventions envision, rejecting a rigid "prosecute and imprison" stance that some have argued is required under the conventions. As the International Narcotics Control Board has observed, the Conventions are highly respectful of domestic law, and each country's unique circumstances affect how it implements its Convention obligations. In particular, article 36 of the Single Convention acknowledges "constitutional limitations" as a constraint. The Conventions, as they have evolved in practice, show the capacity to permit variations in national law and policy. In the case of the United States, constitutional limitations are a major factor, given the interplay of Federal and state-level laws and authorities on drug control issues.

The Conventions also explicitly authorize countries to provide alternatives to prison for drug users and low level drug-involved offenders. Thus, for example, inherent in the Conventions is sufficient flexibility for countries like the United States to differentiate sentencing policy between significant drug traffickers and violent criminals and drug-involved nonviolent offenders, who are more appropriately directed into alternatives to incarceration that can concurrently address substance use problems and protect public safety.

3. In August 2013, the Department of Justice issued "the Cole Memorandum" which delineated eight priority enforcement areas related to marijuana. This memo also emphasized that states must implement "strong and effective regulatory and enforcement systems" to ensure that their laws legalizing marijuana "do not undermine federal enforcement priorities."

    - *Is ONDCP working with its federal counterparts to ensure that states have implemented strong and effective regulatory and enforcement systems? If so, what metrics are being used to make this determination? If not, why not?*

ANSWER: ONDCP, with its Federal partners, is monitoring the consequences to public health and safety of state laws that legalize marijuana.

We are also in contact with Colorado and Washington and have encouraged them to enhance their ability to track the impacts of their legislation. For example, we have encouraged them to work with their community hospitals to obtain data on marijuana-related emergency department visits to assess the degree to which marijuana use may result in acute health problems. We also have asked that they maintain and make publicly available data on sales and tax receipts for use in econometric analyses of the consumption of marijuana and related consequences.

As sales of state-regulated marijuana and marijuana-containing products began in Colorado in January 2014 and in Washington in July 2014, it is too early to assess the public health and safety impact of such sales in these two states.

Most of the data systems the Government is relying upon to assess the impact of these laws collect data on an annual cycle. In most cases, results for 2014 will not be available until 2015. Neither state has yet to release data from their own data systems on the post-implementation period.

- *It is my understanding that data related to the public health and criminal justice impacts of marijuana legalization in Colorado and Washington State can be culled from a number of existing sources. As the federal agency responsible for national drug control, is ONDCP working with its counterparts to create a singular document that will provide a complete picture of the public health and criminal justice impacts of the laws in these states? If not, why not?*

ANSWER: ONDCP and its partners will be collecting and analyzing data for the entire country, for the states in question, and for states that border those that have implemented commercialization programs that increase access to marijuana, to the extent that the data systems permit analysis at the state level.

For example, the Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health permits state-level estimates of many variables, including the prevalence of use of marijuana and perceptions of harm and disapproval. These data can be analyzed by age and other demographic variables. The National Highway Traffic Safety Administration's Fatal Analysis Reporting System provides state-level data on fatal traffic crashes, including whether drugs were involved.

ONDCP does not anticipate producing a "singular document" report on the impact on public health and safety of these laws. All of the relevant Federal data systems are on different collection and reporting cycles. ONDCP and its Federal partners will report on the data, including those relevant to assessing the impact of these state marijuana legalization laws, as the data are available for release. This process will provide more timely information on the potential impact of these laws.

4. As Chairman of the Senate Caucus on International Narcotics Control, it is clear to me that the United States needs more effective drug treatment programs. However, experts have stated said that only a fraction of the Americans who show signs of substance abuse get the treatment they need. One of the causes for this gap may be the 16 bed limit on treatment centers that accept Medicaid patients.

    - *Do you believe that the 16 bed limit for substance abuse treatment facilities that accept Medicaid patients should be lifted?*

This issue is very important as we work to expand substance use disorder services and increase patient access. A major consideration of whether or not the limit should be lifted is recognizing that the demand for substance use disorder services continues to increase, while the number of providers in many communities is lacking. Given this, the 16-bed patient limit creates a barrier for people to access the care they need to treat their substance use disorders.

People need to have the opportunity to receive the right care at the right time, and in the right setting to treat their substance use disorder. Medicaid beneficiaries with substance use disorders are a vulnerable population, often have low incomes, and have complex chronic illnesses and medical comorbidities needing access to a range of healthcare services. Therefore, efforts to expand, and not limit, services and patient access is critical to address substance use disorders and the health of the people with these disorders across our Nation.

The Centers for Medicare and Medicaid Services (CMS) is conducting a study to assess the impact the 16-bed limit may have on treatment access. A report on the study's findings will be released in the coming months.

In addition to addressing treatment capacity, it is also necessary to establish industry standards for placement, continued stay, and transfer/discharge of patients with substance use disorders and co-occurring conditions. Once standards are formulated and adopted, accrediting and licensing entities need to work with service delivery providers to ensure compliance.

- *While this limit remains in place, is there a way to work administratively to ensure that more Americans who seek treatment receive it?*

To support substance use disorder treatment efforts across the Nation, ONDCP has created and leads an interagency workgroup, the Treatment Coordination Group (TCG). The TCG is charged with the following:

- Coordinating and synchronizing efforts of Federal partners who play a role in supporting the substance use disorder treatment services described in the *National Drug Control Strategy*;
- Increasing comprehension of the landscape of treatment for substance use disorders;
- Ensuring the adoption of quality evidence-based services and systems of care across Federal agencies and contractors;
- Developing and promoting opportunities among Federal partners to expand access to treatment services for substance use disorders;
- Ensuring that agency, programmatic, and interagency data (performance, research, etc.) inform discussions and decisions; and
- Sharing insight and experience to address issues pertaining to treatment for substance use disorders.

The Federal partners in the TCG have agreed to synchronize individual agency efforts to:

- Ensure access to substance use disorder treatment, including medication-assisted treatment, is improved,
- Increase in the quality of treatment services delivered; and
- Have systems in place to monitor adequately the outcome of these services.

Each TCG agency has reported to ONDCP on short-term and long-term activities and progress on expanding access to treatment and on ensuring that people have access to the continuum of recovery and support services.

An example of the efforts of a partner in the TCG is CMS's Medicaid Innovation Accelerator Program (IAP). Based on its work with states and stakeholders, CMS identified substance use disorders as an area of focus for IAP efforts. As part of a strategy to improve the care and outcomes for individuals with substance use disorders, CMS works with states to leverage IAP resources to introduce system reforms that better identify individuals with substance use disorders, expand coverage for effective substance use disorder treatment, and enhance substance use disorder practices delivered to beneficiaries.

Finally, we cannot forget that the Affordable Care Act (ACA) allows expanded access to substance use disorder services. This is a significant change to the way services for substance use disorders can be delivered, which historically has been through a separate delivery system only for the most chronic patients. Full implementation of the ACA gives many more Americans in need of substance use treatment an opportunity to be treated.

Senate Committee on the Judiciary
Nominations Hearing
November 13, 2014

United States Senator Mazie K. Hirono

Questions for Mr. Michael Botticelli:

1) Mr. Botticelli, earlier this Congress this Committee looked at ways to alleviate the stress currently placed on our overburdened Bureau of Prisons. One issue we discussed was a reduction of mandatory minimum sentences for low-level, non-violent drug offenses. Do you have a position on reducing the mandatory minimums in these instances?

ANSWER*:* Sentencing reform is urgent because prison spending has increasingly displaced other important public safety investments, such as resources for investigation, prosecution, prevention, intervention, substance use and mental health treatment, prisoner reentry, and aid to local law enforcement. It is important, therefore, that we revise penalties for certain low-level, non-violent drug offenses while maintaining significant penalties against kingpins, drug and gang organization leaders, violent defendants, and those who possessed a firearm or dangerous weapon. This balanced approach would continue to keep our communities and streets safe.

2) Mr. Botticelli, can you tell me a little more about the Office of National Drug Control Policy's prescription drug plan to reduce improper use of prescription drugs?

ANSWER: The Obama Administration released the Prescription Drug Abuse Prevention Plan (the *Plan*) in 2011. The *Plan* was developed in conjunction with other Federal agencies, to include the Department of Justice (DOJ) and the Department of Health and Human Services (HHS) and established specific action items. The *Plan* focused primarily on preventing prescription drug abuse and was intended to be an adjunct to the *National Drug Control Strategy* (the *Strategy*). The *Strategy*, released annually by ONDCP, provides a framework for reducing drug use and its consequences through prevention, treatment, support for recovery, criminal justice reform, law enforcement efforts and international supply reduction efforts.

<u>The *Plan* in Brief</u>

The *Plan* includes four pillars:

- **Education.** A crucial first step in tackling the problem is to educate parents, youth, and patients about the dangers of abusing prescription drugs, while educating prescribers on the appropriate and safe use, and proper storage and disposal of prescription drugs.

- **Monitoring.** Implement prescription drug monitoring programs (PDMPs) in every state to reduce "doctor shopping" and diversion, and enhance PDMPs so they share data across states and are used by healthcare providers.
- **Proper Medication Disposal.** Develop convenient and environmentally responsible prescription drug disposal programs to help decrease the supply of unused prescription drugs in the home.
- **Enforcement.** Provide law enforcement with the tools necessary to eliminate improper prescribing practices and reduce the number of pill mills.

Progress to Date

One of the most significant signs of progress under the plan is that the rate of current illicit drug use among adolescents was down 13 percent from 2009, largely due to decreases in prescription drug abuse. Decreasing the number of new initiates will lead to long-term decreases in the number of individuals with chronic prescription drug abuse problems.

Progress has been made in each of the four pillars:

- **Education:** Prescribers who work in the Federal Government in clinical roles at HHS, DOJ, and the Department of Defense are completing continuing education on substance abuse. Drug manufacturers have provided funding for grants to support safe prescribing of extended-release, long-acting opioids through the Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS) for these drugs. The FDA has set a goal of training 80,000 prescribers evaluating the program's effectiveness for changing prescribing behavior by the end of 2015. The Federal Government has supported a variety of free or low-cost options online, such as NIDAMED,[1] Do No Harm,[2] and Scope of Pain,[3] with continuing education credits options for prescribers.
- **Monitoring:** In 2011 when the *Plan* was released, only 35 states had electronic PDMPs. In these states, the registration and use by prescribers was low.[4] Today, 49 states have operational PDMPs, and the District of Columbia has legislation authorizing a PDMP. There has been considerable activity to begin facilitating information sharing among some of these PDMPs.
- **Proper Medication Disposal:** The Drug Enforcement Administration (DEA) has held nine National Take-Back Days, and during these over 2,411 tons of medicines has been collected.[5] On September 9, 2014, DEA published its final rule on controlled

[1] NIDAMED CME training website linked to on 11/13/2014. http://www.drugabuse.gov/opioid-pain-management-cmesces?utm_source=National&utm_medium=Web-Badge&utm_content=October-2012&utm_campaign=NIDA-eTools
[2] Do No Harm website linked to on 11-13-2014. http://cme.usuhs.edu/medication-misuse-program/cme-USUAM5.html
[3] Scope of Pain Website linked to on 11-13-2014. https://www.scopeofpain.com
[4] ONDCP Fact Sheet on Prescription Drug Monitoring Programs Released 4-8-2011 available at http://www.whitehouse.gov/sites/default/files/ondcp/Fact_Sheets/pdmp_fact_sheet_4-8-11.pdf linked to on 11-13-2014
[5] http://www.dea.gov/divisions/hq/2014/hq110514.shtml

pharmaceutical drug disposal in the *Federal Register*, effective October 9, 2014. DEA plans to sunset its Take-Back Days program in favor of local community-supported disposal options permitted under the final rule. In anticipation, ONDCP and DEA have begun educating stakeholders about the new options for year-round disposal programs through trainings and other educational programs.

- **Enforcement:** Since 2009, the National Methamphetamine and Pharmaceuticals Initiative, an initiative of ONDCP's High Intensity Drug Trafficking Areas Program, has provided training to over 26,000 law enforcement and criminal justice professionals. DOJ enforcement efforts in Florida reduced the number of pill mills significantly over the last four years.

Resulting New Activity from the *Plan*

The National Governor's Association (NGA), the Association of State and Territorial Health Officials (ASTHO), the National Association of Attorneys General, and others have all invited ONDCP to engage with their members on these issues. NGA and ASTHO have worked with ONDCP and HHS to lead policy academies to assist state teams to develop their own prescription drug abuse prevention plans with Governor or State Health Department Commissioner support.

In addition, ONDCP is working with HHS and DOJ to expand access to the opioid overdose prevention medication naloxone, both for first responders and community groups. HHS (through its Substance Abuse and Mental Health Services Administration) and DOJ (through its Bureau of Justice Assistance) both released toolkits to help with the development of naloxone programs for first responders and community groups.

Conclusion

There is evidence the *Plan* is making a difference. A study of likely drug diversion showed a decrease from 2008 to 2012.[6] The latest available (2012) mortality data from the Centers for Disease Control and Prevention shows the first decline in the rate of fatal overdoses involving prescription opioids in over a decade.[7]

[6]Simeone, R. Doctor Shopping Behavior and the Diversion of Opioid Analgesics: 2008-2012 August 14, 2014. ONDCP Report. Available at http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/opioid_diversion_08142014.final.pdf
Linked to on 11-13-2014

[7] Source: National Center for Health Statistics/CDC, National Vital Statistics Report, Final death data for each calendar year (Oct 2014).

Michael Botticelli Nomination Hearing

Questions for the Record from Ranking Member Charles E. Grassley

1. Obama Administration Mixed Messages on Marijuana

Earlier this year President Obama stated he thought recreational use of marijuana was merely a "bad habit" that was no more dangerous than consuming alcohol. He also indicated that he thought that it was "important" for the legalization of recreational marijuana under state law in Colorado and Washington to "go forward." Attorney General Holder has also recently stated that he's "cautiously optimistic" about the legalization of recreational marijuana in those states. Finally, the President recently installed an advocate for legalization of recreational marijuana, Vanita Gupta, as acting Assistant Attorney General for Civil Rights.

a. Do you think these comments and actions by prominent figures such as the President and the Attorney General have contributed to the recent well-documented reduction in the perception of risk related to recreational marijuana use among young people?

ANSWER: The perception amongst youth of the harmfulness of marijuana has been steadily declining since 2005, according to two widely recognized national surveys, the Monitoring the Future survey supported by the National Institute on Drug Abuse (NIDA) and the National Survey on Drug Use and Health from the Substance Abuse and Mental Health Services Administration.

b. If confirmed as head of ONDCP, what specific steps will you take to help reverse this reduction in the perception of risk?

ANSWER: I will work to bolster our prevention efforts through our Drug Free Communities (DFC) Support Program and through the High Intensity Drug Trafficking Areas (HIDTA) program.

ONDCP funds the DFC Support Program, a powerful tool supporting drug prevention efforts in communities nationwide. The program currently provides grants to approximately 680 local drug-free community coalitions, enabling them to increase collaboration among community partners, including local youth, parent, business, religious, civic, law enforcement, and other groups, to prevent and reduce youth substance use, including marijuana use.

DFC coalitions across the country have identified marijuana as a significant problem in their communities. Nearly 90 percent of Fiscal Year (FY) 2013 DFC coalitions list marijuana as one of their top five targeted substances, and are taking action to prevent young people from using

the drug.[1] These coalitions employ a host of prevention strategies, including disseminating multi-lingual educational materials, hosting drug-free social events for youth, working with schools and educators to promote drug-free campuses, and working with local media to highlight prevention activities.

Evaluation data indicate that where DFC dollars are invested and coalitions operate, youth substance use is lower. Between 2002 and 2012, DFC communities have experienced reductions in use of alcohol, tobacco, and marijuana among both middle school and high school students. And in DFC communities, both middle and high school students' perception of parental disapproval of marijuana also increased significantly among all grantee cohorts.[2]

All of these results suggest that DFC community coalitions play a significant role in decreasing marijuana use and changing attitudes for the better among young people across the country.

ONDCP recently announced the FY 2014 DFC grants, including $24.8 million in new grants to 197 communities and 3 new DFC Mentoring grants across the country. These awards join the $59.1 million in DFC continuation grants released to 463 currently-funded DFC coalitions and 17 DFC Mentoring continuation coalitions.

ONDCP also administers the HIDTA program, which provides assistance to Federal, state, local, and tribal law enforcement agencies operating in areas determined to be critical drug trafficking regions of the United States.

Although the HIDTA program's primary mission is to dismantle and disrupt drug trafficking organizations, expanding prevention efforts offer HIDTAs the ability to address the drug threat in a community in a more balanced fashion. Currently, 22 HIDTAs, including all 5 Southwest Border HIDTA Regions, sponsor prevention activities. Nine HIDTAs specifically target marijuana, among other substances, in their prevention efforts.

2. Cannabidiol

Last year, the Food and Drug Administration (FDA) approved clinical trials for Epidiolex, a highly-concentrated form of cannabidiol (CBD), for the treatment of rare forms of epilepsy. As you know, CBD is a non-psychoactive component of marijuana. Many people throughout the country and in Iowa, especially young children, are afflicted with severe cases of intractable epilepsy that anecdotal evidence suggests may be effectively treated with CBD. Research related to the potential medical benefits and risks associated with CBD could help determine whether this is so.

[1] Unpublished Drug Free Communities Support Program Evaluation Tracking.
[2] Ibid, pg. 19

a. Do you support research into the potential benefits and risks associated with the administration of CBD to treat patients such as these?

ONDCP supports the efficient and scientific assessment of CBD in connection with potential new drug development and is supportive of FDA efforts, consistent with Federal Food, Drug, and Cosmetic Act and the Controlled Substances Act (CSA), to expeditiously provide safe and effective medicine to address urgent healthcare needs. It is important that the product be studied under appropriate protocols and submitted to the FDA in an IND application, so that there are assurances of the manufacturing quality of the drug.

In June 2014, FDA granted Fast-Track designation to the investigational CBD product Epidiolex being developed for the treatment of this rare form of childhood epilepsy. FDA has also authorized use of it as a part of an expanded access program, designed to facilitate the availability of investigational drug products to patients while those drugs are being studied for approval. According to the drug manufacturer, there are now 21 active expanded access INDs for Epidiolex treating about 300 patients with epilepsy syndromes. Approximately 95 percent of these INDs are for patients between 1 and 17 years of age.

The Federal Government will continue to support research on how marijuana compounds such as CBD may be used safely and effectively as medicine.

b. How can such research be carried out under the current legal and regulatory framework for approving drugs in the United States?

Marijuana contains compounds with the potential to provide new treatments for important diseases, and the Administration is facilitating scientifically rigorous investigations to learn more about potential therapeutic benefits.

The Department of Health and Human Services (HHS) has approved or supported several hundred research projects for marijuana and its constituent compounds and continues to encourage research in this area, including potential therapeutic benefits.

Research on the therapeutic effects of marijuana or its constituents is being supported by various Institutes of the National Institutes of Health, as related to their missions. NIDA is one of the main supporters of such research, particularly as it relates to the development of less or non-addictive treatments for pain or treatments for addiction.

To support additional research, in May the Drug Enforcement Administration (DEA) approved an increase in the Government's research quota from 21 kilograms to 650 kilograms this year in order to provide a continuous and uninterrupted supply of marijuana to support researchers approved by the Federal Government.

The Administration, through the FDA's Expanded Access Program, also supports access to investigational new drugs outside of a clinical trial by patients with serious or life-threatening conditions who do not meet the enrollment criteria for the trial. Recently, the manufacturer of the new investigational drug Epidiolex announced the availability of expanded access for the treatment of patients with epilepsy.

The Single Convention on Narcotic Drugs of 1961 is an international treaty to prohibit production and supply of specific drugs and of drugs with similar effects except under license for specific purposes, such as medical treatment and research. The Convention requires parties to establish a government agency to control cultivation of drugs such as cannabis.

In the United States, NIDA fulfills that function through a contract with the University of Mississippi to grow cannabis; this is the only legal source of cannabis for medical and research purposes in the United States under Federal law. NIDA supplies this marijuana for Federally and non-Federally funded research projects.

Until recently, research requests indicated a particular interest in studies involving THC, but there is growing interest in marijuana that contains CBD as well. To be responsive to this interest, NIDA has grown a crop of marijuana this year, which is currently being harvested and processed, with varying levels of THC and CBD to meet the demands of the research community. NIDA will continue to grow additional quantities of marijuana with varying THC and CBD levels as the needs require, with appropriate DEA approvals.

c. Are there any legal or regulatory barriers to CBD research that you believe could be responsibly eliminated or changed in order to facilitate this research?

ANSWER: I welcome the opportunity to work with you and with relevant Federal agencies to identify ways to remove barriers and stimulate research on CBD.

3. Diversion of Marijuana from Colorado to Iowa

The Cole Memorandum of August 2013 suggests that the Department of Justice will not seek to enforce the Controlled Substances Act in states that legalize recreational marijuana, except to enforce certain federal priorities, so long as those states implement effective regulatory schemes. Those priorities include the diversion of marijuana from Colorado to other states.
But in 2010, Colorado was the source state for 10% of all marijuana interdicted in Iowa. That number grew to 25% in 2011, and to 36% in 2012. This is all ***before*** legalization of recreational use there. In the words of Colorado's Attorney General, the state is becoming "a significant exporter of marijuana to the rest of the country."

a. What steps can the Administration take to help protect Iowa from the increasing diversion of marijuana from Colorado to it and other states?

ANSWER: ONDCP is not an enforcement agency, but one of the eight enforcement priorities that the Deputy Attorney General describes as "particularly important to the federal government" in his August 29, 2013, memorandum is, "preventing the diversion of marijuana from states where it is legal under state law in some form to other states."

As set forth in the Deputy Attorney General's memorandum, DOJ expects that all jurisdictions that have enacted laws legalizing marijuana in some form will also establish strong and effective regulatory and enforcement systems to control the cultivation, distribution, sale, and possession of marijuana, and to protect against the harms identified in the memorandum. DOJ will use its limited prosecutorial resources to enforce the law in all states in a manner that most effectively addresses its enforcement priorities and ensures public health and safety.

The increase in cross border trafficking that you describe is a serious concern. In fact, the Rocky Mountain HIDTA has identified the diversion of marijuana from Colorado to other states, including Iowa, as an emerging threat and has contacted law enforcement partners in other states to request voluntary reporting of instances in which marijuana from Colorado was seized in their jurisdiction. In 2013, there were 288 Colorado marijuana interdiction seizures destined for other states, compared to 58 in 2008—a 397 percent increase. Of the 288 seizures in 2013, there were 40 different states destined to receive marijuana from Colorado.

Consistent with the mission of the National HIDTA program, the Rocky Mountain HIDTA focuses its efforts on dismantling or disrupting drug trafficking and money laundering organizations. The Rocky Mountain HIDTA identifies domestically-produced marijuana as a key area of concern. In Colorado, the Rocky Mountain HIDTA supports 13 task forces focusing on disrupting or dismantling drug trafficking organizations, including marijuana-trafficking organizations, in the most effective and efficient manner.

Working at the other end of this diversion activity, the Midwest HIDTA, which includes jurisdictions in Iowa, provides a coordinated strategy to identify, disrupt, and dismantle drug trafficking organizations. The Midwest HIDTA supports co-located Federal, state and local task forces and strives to work Federal level investigations and identified priority targets. These task forces typically work priority poly-drug organization cases.

The HIDTA Program has established a Domestic Highway Enforcement (DHE) Strategy, which provides funding and support to primarily State Police and State Highway Patrol interdiction efforts to enhance coordinated multi-jurisdictional law enforcement efforts on the Nation's highways. One such DHE initiative is the Iowa Interdiction Support initiative. The Midwest HIDTA DHE strategy focuses on drug trafficking organizations, including those trafficking in Colorado-sourced marijuana.

In addition, the Iowa Division of Narcotics Enforcement (DNE) has received support from the Midwest HIDTA for use by the Iowa State Patrol and DNE for Domestic Highway Enforcement. The enhanced interdiction efforts have been very successful, with seizures of sizable quantities of controlled substances and bulk cash shipments. More importantly, the intelligence gathered has aided in further identifying drug trafficking organizations and has produced information in furtherance of conspiracy investigations.

The DNE also has numerous officers assigned to DEA and other Federal task forces to facilitate interdiction and other enforcement efforts that cross jurisdictional authorities. The goal in every investigation is to identify the source, location, and destination of the supply. Emphasis is placed on sharing of information and consulting data systems to determine if the target of the interdiction investigation is also a target or co-conspirator in some other existing case or investigation.

The DNE is a participant in all the HIDTA Task Forces operating within the state. The DNE has a network of agents and offices throughout the state that enhance communication and coordination with a wide variety of agencies on the federal, state, and local level. The agents work with the DEA, United States Attorneys, and local prosecutors on a regular basis.

b. If confirmed as head of ONDCP, what specific steps will you take to do so?

ANSWER: ONDCP is not an enforcement agency.

ONDCP will continue to lead interagency efforts to collect and analyze data to assess the public health and safety consequences of state legalization laws, including data on the effects on other states. I will also continue to robustly support the efforts of our HIDTAs and law enforcement agencies to prevent diversion to other states.

4. U.N. Conventions on Narcotic Drugs

As you know, the United States is a signatory of the U.N. Conventions on Narcotic Drugs, which limit the production, distribution, possession and use of narcotics, including marijuana, to scientific and medical purposes. However, in a March 2014 report, the International Narcotics Control Board concluded that the laws in Colorado and Washington legalizing recreational marijuana use were "not in conformity" with these treaties. Moreover, in October 2014, Ambassador William Brownfield, the Assistant Secretary of State for the Bureau of International Narcotics Control and Law Enforcement Affairs, outlined what he described as the "four pillars"

of U.S international drug policy. These pillars included advocating for a "flexible interpretation of the U.N. Conventions" and "tolerating different national drug policies."[3]

a. Do you believe the United States is currently in compliance with its treaty obligations outlined in the U.N. Conventions, despite the legalization of marijuana under the laws of various states? Why or why not?

ANSWER: While the consequences of legalization measures in four states are a serious concern, United States compliance with the Conventions has not changed. The United States is firmly committed to upholding our obligations under the three U.N. drug conventions, as well as working with international partners to promote the goals of those conventions. These conventions are the foundation of international cooperation for dealing with all aspects of the drug problem, and we support them unwaveringly.

We believe that the policies set forth in the UN Drug Conventions limiting access to controlled substances for medical and scientific purposes are sound, and based on valid health concerns. The United States has opposed efforts to alter the Conventions.

Under Federal law, marijuana remains a Schedule 1 drug, subject to a high level of control, with criminal penalties for its illegal distribution and sale. Per the requirements of the Conventions, as well as our domestic laws, the U.S. Government heavily emphasizes proactive enforcement of laws against drug production and trafficking, as well as related money laundering, violence, and other illegal activities that impact the safety of our citizens. We lead the world in efforts against international drug cartels wherever they operate, and have – with the strong support of the Congress over many years - provided training, technical assistance, and other aid to key partners around the world, especially in the Western Hemisphere to help them disrupt and dismantle these organizations.

The Federal Government has enforced and is enforcing Federal drug laws within existing resources and allows prosecutors appropriate discretion to prioritize cases. In the Memorandum from Deputy Attorney General Cole dated August 29, 2013, DOJ has articulated eight Federal enforcement priorities with respect to cannabis and is currently investigating and has prosecuted criminal enterprises involved in marijuana trafficking and violence in all areas of the country.

As the International Narcotics Control Board (INCB) has observed, the Conventions are highly respectful of domestic law, and each country's unique circumstances affect how it implements its

[3] The "four pillars" of U.S. international drug policy were described as: (1) respecting the existing U.N. Conventions; (2) accepting flexible interpretation of the U.N. Conventions; (3) tolerating different national drug policies; and (4) combating and resisting criminal organizations. *See* William R. Brownfield, Asst. Sec'y, Bureau of Int'l Narcotics and Law Enforcement Affairs, U.S. Dep't of State, Briefing on Trends in Global Drug Policy (Oct. 9, 2014) (transcript available at http://fpc.state.gov/232813.htm).

Convention obligations. In particular, article 36 of the Single Convention acknowledges "constitutional limitations" as a constraint. The Conventions, as they have evolved in practice, show the capacity to permit variations in national law and policy. In the case of the United States, constitutional limitations are a major factor, given the interplay of Federal and state-level laws and authorities on drug control issues.

The Conventions also explicitly authorize countries to provide alternatives to prison for drug users and low-level drug-involved offenders. Thus for example, inherent in the Conventions is sufficient flexibility for countries like the United States to differentiate sentencing policy between significant drug traffickers and violent criminals - deserving of stiff penalties and long prison sentences - and drug-involved nonviolent offenders, who are more appropriately directed into alternatives to incarceration that can concurrently address substance use problems and protect public safety.

b. What do you believe will be the impact of the State Department's policy, as set forth in Ambassador Brownfield's remarks, on U.S. efforts to continue as an international leader on drug control issues?

ANSWER: The Four Pillar framework is an effort to stake out a middle ground between those who believe that prosecution and jail is the only approach and those favoring radical changes to the conventions. The pillars advocate for preservation of the integrity of the conventions while accepting innovation at the national level and prioritizing cooperation against transnational organized crime. This is wholly consistent with the mandates of the conventions, which are highly respectful of domestic law while providing the tools for cooperating on controls, sharing best practices, and expanding access to essential medicines.

While our international partners are interested in the impacts of the actions taken at the state level with regard to marijuana, policies by U.S. states have not had an impact on our ability to work bilaterally and multilaterally on a range of drug issues. Countries continue to support the key areas we emphasize in our *National Drug Control Strategy*, such as strengthening international capacities to reduce drug production and trafficking, increasing efforts on public health solutions to drug use, promoting sentencing reforms that include reduced and alternative sentences for non-violent, low-level offenders with substance use disorders, and using science and evidence to guide drug policies. Our international partners also continue to recognize the urgent threats posed by transnational organized crime, and the need for strengthened international responses.

We will continue to support global efforts to reduce the global drug problem and champion a balanced approach to reduce the demand for drugs and combat trafficking.

c. If confirmed as Director of ONDCP, what specific steps will you take to ensure that the United States remains a leader on international drug control issues?

ANSWER: The United States is a recognized leader in developing and promoting evidence-based drug abuse prevention and treatment programs and provides millions of dollars of funding and technical assistance to countries to support their efforts to prevent and reduce drug use and substance use disorders. We support most of the world's research on the health aspects of drug abuse and addiction, and also lead the world in efforts against international drug cartels wherever they operate, and have – with the strong support of the Congress over many years – provided training, technical assistance, and other assistance to build the criminal justice capacities of key partners around the world, especially in the Western Hemisphere, to help them disrupt and dismantle these organizations.

ONDCP, in close collaboration with the Department of State and other agencies, works multilaterally to demonstrate U.S. leadership on international drug control issues and shares best practices and research with the international community. One opportunity to ensure that the United States remains a leader on international drug control issues is at the annual United Nations Commission on Narcotics Drugs (CND). Under my direction, ONDCP is working on an ambitious agenda for the next CND meeting in March 2015.

Earlier this year, as Acting Director, I co-led the U.S. delegation to the CND, to actively promote balanced and effective drug policies under the framework of the U.N. Conventions. We conducted the following activities:

- Drafted and pushed through to enactment CND resolutions on the need for an international response to new synthetic drugs and on the importance of recovery;
- Spoke at six side events, including ones on alternatives to incarceration, drugged driving, synthetic drugs, overdose prevention, and international demand reduction;
- Held more than 10 bilateral meetings with a wide range of governments;
- Co-Chaired with Sweden an eight-country multilateral breakfast meeting on the importance of maintaining the current U.N. Drug Control Conventions;
- Participated in a high level dialogue with the United Nations Office of Drugs and Crime (UNODC) and INCB leadership;
- Conducted a patient and constructive approach on the negotiation of texts, including the longer Joint Ministerial Statement and all the other CND resolutions, to highlight U.S. positions and reject policies which advance drug legalization.

In meetings with counterparts in the international community, the United States will continue to emphasize that marijuana remains illegal under Federal law; reaffirm its strong support for the three U.N. drug conventions, and reinforce its commitment to reduce and prevent drug use,

including marijuana. We will continue to support global efforts to reduce the drug problem and champion public health interventions to reduce the demand for drugs and continuing efforts to stop trafficking and reduce supply.

5. Methamphetamine

The number of methamphetamine laboratory incidents is a at a seventeen-year low in Iowa, perhaps in part due to law enforcement tracking the sales of pseudoephedrine. However, the quantity of the drug itself being seized there is at a nine-year high. Much of this methamphetamine appears to be being trafficked into Iowa from Mexico. Indeed, in 2013, more than half of Iowa's drug related prison admissions were methamphetamine-related. Also in 2013, methamphetamine abuse constituted fifteen percent of all publicly-funded treatment entries, which is an all-time high percentage for Iowa.

a. What more can the Administration do to prevent the trafficking of methamphetamine and other drugs coming from the southwest border into Iowa?

ANSWER: ONDCP is very concerned about current trends for methamphetamine production, trafficking, and consumption, and the Administration is working on this issue on multiple fronts. Although we do not have state-by-state breakouts from the National Survey on Drug Use and Health, the national trends suggests a statistically significant increase in adult consumption of methamphetamine between 2010 and 2013. The longstanding problem of small domestic laboratories, although still a major threat to public and officer safety, appears to be on the decline. According to reporting from the National Methamphetamine and Pharmaceutical Initiative (NMPI), which is supported by ONDCP's HIDTA Program, domestic laboratories and labs sites located have dropped from over 15,000 in 2010 to less than 7,000 in 2014 (as of the end of October). This reduction is likely a result both of retail restrictions on the sale of pseudoephedrine and the increased availability of methamphetamine produced in Mexico and smuggled across the Southwest Border. Southwest Border seizure trends over the past five years suggest a troubling increase in the flow of methamphetamine into the United States. For example, U.S. Customs and Border Protection seizures in California increased from 2,173 kilograms in 2009 to 7,255 kilograms in 2013, a more than 300 percent increase.

Although past efforts to control international diversion of pseudoephedrine and ephedrine, as well as combination products containing these substances, were relatively effective a decade ago, methamphetamine manufactures have changed their methods of production and resorted to what is known as the P2P method that does not require ephedrine. The P2P (1-phenyl-2-propanone) method employs different chemicals, sometimes referred to generally as "pre-precursors." They pose a very significant challenge to law enforcement agencies seeking to track and seize them because they are not internationally controlled. Even if one of these chemicals is on a watch list, interdiction efforts are evaded through mislabeling or outright smuggling. They are getting into

Central America and Mexico in large quantities and being turned into methamphetamine for consumption in the United States.

A number of steps are currently being taken by the Administration to combat this threat to the United States. Specifically, the Administration is engaging with China and India, two of the main precursor source countries, to improve international controls of precursor chemicals. In addition to working bilaterally, we are working multilaterally with the UNODC and the INCB to tighten international control mechanisms to prevent the diversion of precursor chemicals from legitimate international commerce. In addition, the Administration is working to improve the capacity of Mexico and Central American nations to detect and seize diverted precursors. DEA is also working closely with Mexican law enforcement to better identify and destroy "superlabs" and to disrupt and dismantle the organizations which produce and traffic methamphetamine. Moreover, this Administration is providing training and technical assistance to the Central American nations to improve precursor disposal capabilities in the region. The disposal issue is critical because partners without a safe way to dispose of vast amounts of seized chemicals will inevitably reduce their efforts at detection and seizure.

b. If confirmed as Director of ONDCP, what specific steps will you take to address this problem?

ANSWER: Given the circumstances set out above, Iowa and the rest of the United States face an ongoing serious challenge with regard to methamphetamine production and trafficking. I am committed to pushing the U.S. interagency and our international partners to address it as a high priority. I will continue to support demand reduction efforts to prevent and treat methamphetamine use, a highly addictive drug. I will also advocate continued support of the NMPI as well as other efforts in the Federal interagency to reduce methamphetamine use and its consequences, such as methamphetamine cleanup funds provided through DOJ. I look forward to continuing to work with Congress to address this problem which directly threatens the health and safety of our citizens.

6. Synthetic Drugs

As you know, synthetic drugs remain a vexing problem for both law enforcement and public health officials. One aspect of the challenge they pose is that many of these drugs are manufactured in China and then imported into the United States.

a. What more can the Administration do to prevent importation of synthetic drugs, either through engaging the Chinese government or to interdict them at the border?

ANSWER: Synthetic drugs are indeed a vexing problem. The use of New Psychoactive Substances (NPS) is a problem not just in the United States but around the world. Over the past several years, the United States, like our partners in Europe, has been inundated with more than 250 designer synthetic drugs, challenging our capability to keep up with ever-changing chemical formulas. Manufactured in labs overseas, these drugs are unregulated and can be extremely dangerous to consume. As noted in the question, most of the raw components for these substances originate in China. The previous Director of National Drug Control Policy, R. Gil Kerlikowske, led an interagency counterdrug visit to China in 2012, during which (in addition to addressing methamphetamine precursor issues) he highlighted the Administration's concern about Chinese production and transshipment of the raw chemical components of NPS. During that visit, and after – via the DEA Office in Beijing – the United States has urged China to: ban the production and trafficking of NPS in their domestic laws; collaborate with the U.S. Government and other governments to promote international control of these substances; and work with the United States on specific cases related to NPS produced in China. There has been some incremental progress, but it has not been as rapid as we would like.

b. If confirmed as Director of ONDCP, what specific steps will you take to address this problem?

ANSWER: We will continue to push for international scheduling of NPS through the World Health Organization and will, under the Department of State's leadership, collaborate with the other G-7 countries to accelerate international control of these substances. The Department of State is also funding the INCB to organize international operations to track the full supply chain process for NPS. These exercises have proved fruitful in the past in identifying key nodes in the illicit supply chain. In addition to DEA's leadership in working worldwide on the NPS problem, other agencies are also working to track and disrupt the NPS trade. The Department of Homeland Security, in particular, has been working to improve exchange of trade data on chemical products with the goal of identifying and blocking the entry of NPS into the United States. Finally, I know DEA has sought to be responsive to Congressional inquiries on how to facilitate more effective prosecution of NPS producers and traffickers. I am supportive of these discussions and look forward to exploring with Congress how to ensure that our law enforcement agencies have the authorities they need to efficiently disrupt and dismantle those organizations that are threatening the health of our citizens with these dangerous substances.