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"Deadly Synthetic Drugs: The Need to Stay Ahead of the Poison Peddlers"

Committee on the Judiciary
United States Senate

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Introduction

Chairman Grassley, Ranking Member Leahy, and members of the Committee, thank you for inviting the Office of National Drug Control Policy (ONDCP) to discuss the public health and safety threats related to dangerous synthetic drugs.

ONDCP was established by Congress in 1988 with the principal purpose of reducing illicit drug use, manufacturing, and trafficking; drug-related crime and violence; and drug-related health consequences. As a component of the Executive Office of the President, ONDCP establishes policies, priorities, and objectives for the Nation's drug control programs and ensures that adequate resources are provided to implement them. We also develop, evaluate, coordinate, and oversee the international and domestic anti-drug efforts of Executive Branch agencies and ensure such efforts sustain and complement state and local drug policy activities.

At ONDCP, we are charged with producing the *National Drug Control Strategy* (*Strategy*), the Administration's primary blueprint for drug policy, along with a national drug control budget. The *Strategy* is a 21st century plan that outlines a series of evidence-based reforms that treat our Nation's drug problem as a public health challenge as well as a criminal justice issue. It is guided by what science, experience, and compassion demonstrate about the true nature of drug use in America.

The policies and responses promoted in the *Strategy* to prevent drug use and its consequences are a balance of evidence-based public health and safety initiatives that include preventing use, providing care, and stopping production and trafficking of drugs. Despite this comprehensive approach, ONDCP is concerned about whether our traditional responses to drug threats can successfully reduce use and availability of synthetic drugs, specifically new synthetic compounds, in the United States and the consequences to the public if these responses are not effective.

Synthetic Drug Overview

In contrast to botanical drugs, which are derived from plant material, synthetic drugs are manufactured in laboratories using chemicals. Most medications that have been approved by the Food and Drug Administration are, by definition, synthetic drugs, although these are drugs that we use daily to protect and promote health and wellness. These drugs and their legitimate and healthful uses are outside of the scope of the discussion below, which will focus solely on synthetic drugs designed and used for psychotropic rather than therapeutic effects.

There are several drugs that fall under this category. Some, such as MDMA, or Ecstasy *(3,4-methylenedioxy-methamphetamine*), have no known medical use and are Schedule I drugs under the Controlled Substances Act (CSA). Others such as methamphetamine and fentanyl, although very dangerous if misused, are in Schedule II of the CSA because they have medical uses and a high potential for abuse.

New Psychoactive Substances (NPS), such as synthetic cannabinoids, synthetic cathinones, and synthetic hallucinogens, are often not controlled under the CSA or the relevant international drug conventions, have no known medical use, and may pose a serious threat to public health. NPS, sometimes known as "designer drugs" or "legal highs" are designed by

chemists to mimic, with slight structural modifications, the pharmacological (drug-like) effects of controlled substances to circumvent international and domestic drug controls.

Although the estimated number of users of NPS and synthetic drugs like illicit methamphetamine and illicit fentanyl remains relatively low in the United States, use can result in addiction and life-threatening adverse medical consequences. In recent years, we have seen a 95 percent increase in phone calls to poison control centers across the United States related to the use of synthetic drugs, with over 8,000 calls alone in 2015 related to NPS.[1,2]

NPS products in particular, often packaged to appeal to younger users, are a dangerous mix of chemicals, and can cause tragic results for the user. The potency of product can vary significantly from batch to batch even within the same product because of inconsistency in the NPS included and inconsistent concentrations of NPS. Severe effects from synthetic cannabinoids include psychosis, seizures, anxiety, nausea, and vomiting.[3] Synthetic cathinones are pharmacologically similar to amphetamines, cocaine, and MDMA, and can cause a range of effects including lowered inhibition, anxiety, depression, paranoia and hallucinations. They can also raise heart rate and blood pressure. At least one commonly used synthetic cathinone, *3,4-methylenedioxy-pyrovalerone* (MDPV), affects the brain in a manner similar to cocaine but is at least 10 times more powerful.[4] Products sold under the name "Molly" (traditionally containing MDMA) often now contain synthetic cathinones instead. States around the country continue to report overdose deaths and severe health effects associated with NPS.[5,6]

As of December 2015, the United Nations estimated there were over 600 identified NPS available on the global market.[7] The vast majority of these are not controlled under United Nations drug treaties or domestic drug control authorities.

Although the United Nations, the United States Government, and all 50 states and the District of Columbia have developed regulatory responses to control these substances, the rapidity and ease with which NPS, in particular new analogues of recently controlled substances, can be manufactured, makes control through traditional regulatory, legislative, and law enforcement responses challenging.

According to the Drug Enforcement Administration (DEA), almost all NPS are synthesized and manufactured in China. They are marketed over the Internet and shipped to the United States via mail services or supplied to retail distributors and sold to the public at retail stores. These substances are labeled to mask their intended use with statements on the packaging

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[1] Synthetic Cannabinoid Data, American Association of Poison Control Centers, May 31, 2016
[2] Bath Salts Data, American Association of Poison Control Centers, May 31, 2016
[3] Seely, Kathryn A. et al. "Spice Drugs Are More than Harmless Herbal Blends: A Review of the Pharmacology and Toxicology of Synthetic Cannabinoids." *Progress in neuro-psychopharmacology & biological psychiatry* 39.2 (2012): 234–243. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3936256/pdf/nihms550527.pdf
[4] Baumann, Michael H et al. "Powerful Cocaine-Like Actions of 3,4-Methylenedioxypyrovalerone (MDPV), a Principal Constituent of Psychoactive 'Bath Salts' Products." *Neuropsychopharmacology* 38.4 (2013): 552–562. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3572453/
[5] Kasper, A. et al. 2015. Notes from the Field: Severe Illness Associated with Reported Use of Synthetic Cannabinoids — Mississippi, April 2015. Morbidity and Mortality Weekly Report, 64(39); 1121-2; October 9.
[6] Ghosh, T. et al. 2013. Notes from the Field: Severe illness associated with reported use of synthetic marijuana--Colorado, August-September 2013. Morbidity and Mortality Weekly Report, 62(49):1016-1017; December 13.
[7] UNODC Early Warning Advisory on New Psychoactive Substances, 2015. Available at: https://www.unodc.org/documents/scientific/NPS_leaflet_2016_EN_LORES.pdf

such as "not for human consumption" or "for novelty use only." Suppliers aggressively market these substances to end users – and often specifically target the youth market – with logos and patterns drawn from popular culture, and describe them as safe or legal alternatives to traditional illicit drugs.

The bulk of the precursor chemicals used to manufacture illicit methamphetamine and illicit fentanyl also originate in China. The majority of the illicit methamphetamine and illicit fentanyl in the U.S. market is smuggled into the country after being clandestinely produced in Mexico or China.[8]

The Administration engages with regional and international partners to address the dynamic problems caused by the manufacture and use of New Psychoactive Substances and other synthetic drugs. Federal agencies are working closely with China and other countries to reduce the production of these substances as well as precursor chemicals used to manufacture illicit methamphetamine and fentanyl and have been encouraged by recent actions and discussions with the Chinese government.

We are also working with regional and international organizations, such as the United Nations Office on Drugs and Crime (UNODC) and the International Narcotic Control Board, to monitor and reduce the supply of synthetic drugs.

Additionally, Federal agencies are working with the chemical industry and corporate entities to monitor and track the manufacture of synthetic drugs and their precursor chemicals; Congress to improve regulatory tools and schedule newly-identified NPS; and law enforcement to support investigations domestically and abroad. Federal agencies are also working with the science and research community to better understand the pharmacology of NPS and to help inform prevention and treatment interventions, as well as with our prevention partners to educate communities about the dangers of synthetic drugs.

Below is a discussion of areas where focused Federal efforts could result in substantial progress against NPS and other synthetic drugs.

International Efforts

To reduce the availability of NPS in communities in the United States, Federal agencies should continue to work both bilaterally and in multilateral fora with international partners to promote international controls of synthetic drugs and chemicals and other available mechanisms, to reduce production and trafficking of NPS.

International Control

Countries around the world are grappling with how best to reduce the use and availability of synthetic drugs and are exploring ways to enhance international controls and cooperation, as well as domestic opportunities for action.

[8] Drug Enforcement Administration. Strategic Intelligence Section. 2015 National Heroin Threat Assessment. DEA-DCT-DIR-039-15

International control of drugs and chemical precursors is important as it supports countries in their law enforcement actions and domestic scheduling efforts, both of which can result in reduced availability of NPS in the United States. It is ONDCP's position that the international scheduling framework is both underutilized and ill-equipped to review and potentially control expeditiously the large numbers of NPS eligible for consideration.

At the April 2016 Special Session of the United Nations General Assembly on the World Drug Problem, the United States and several other countries strongly encouraged the World Health Organization (WHO) to use their authorities to more effectively review substances, including NPS, for control. To help WHO in this important effort, the United Sates supports, through funding from the Department of State's International Narcotics and Law Enforcement Bureau, an early warning system hosted by the UNODC. This system, collects data on NPS including forensics; prevalence, reported health harms and adverse consequences of use; legislation; and regulations. It also provides forensics assistance to countries to help them quickly identify emerging NPS. The system provides not only a forum to exchange and track information relevant to NPS in real time, but also data that is used by the WHO to review NPS and by the Commission on Narcotics Drugs (CND), a treaty body for the three United Nations drug control conventions, when deciding whether to recommend controlling them under the international drug control treaties.

NPS has been a priority issue for the CND for several years, and Member States have asked WHO to activate its authority to review substances for control to help reduce availability of NPS. In March 2015, for the first time in over a decade, the CND, based on information provided by WHO, recommended scheduling 10 new synthetic substances, including 25B-NBOMe, 25C-NBOME, and 25I-NBOMe. In March 2016, the CND voted to schedule another seven substances, including acetyl fentanyl; MT-45, a powerful opioid analgesic; a-PVP*(α-Pyrrolidino-pentiophenone*), also known as Flakka; and PMMA (*para-Methoxy-N-methylamphetamine)*, an amphetamine-class drug, which has been associated reportedly with deadly overdoses around the world.[9,10,11]

Recognizing the number of currently identified NPS would overwhelm the existing international drug control process, the United States is leading discussions with international partners, including relevant United Nations bodies, on how to be more proactive and less reactive to trafficking organizations and improve the existing international drug control system to better protect public health and safety from these dangerous drugs.

Bilateral Engagements

In addition to multilateral efforts, the United States and international partners are working closely with China in multiple areas to reduce the supply of NPS.

In October 2015, China's Ministry of Public Security announced significant actions to gain control over NPS, which should help reduce supply, including in the United States. China placed 116 NPS under national control, including acetyl fentanyl; streamlined the scheduling

[9] Commission on Narcotic Drugs. Draft report on the fifty-ninth session https://www.unodc.org/documents/commissions/CND/CND_Sessions/CND_59/E2016_28_Advance_unedited_19042016.pdf (pages 52-53). Accessed May 24, 2016.

[10] http://www.emcdda.europa.eu/attachements.cfm/att_33350_EN_Risk5.pdf

[11] http://www.unodc.org/documents/scientific/GSU-11-EN.pdf

process for NPS in the future; and determined that the impact of a substance both domestically and internationally should factor into the review of substances for control.

As China is also a main source of precursor chemicals for the production of illicit methamphetamine and fentanyl, the United States is encouraged that China has expressed interest in developing similar legislation to address the production of precursor chemicals used to synthesize these dangerous drugs.

Although China produces and monitors all of the chemicals listed in the 1988 UN Convention and regulates the import and export of these precursor chemicals, effective regulatory oversight of the chemical industry remains a challenge. For this reason, while the United States continues to encourage China's efforts related to controlled chemicals, the Administration is also urging voluntary cooperation on non-listed chemicals as a priority, because chemists are producing new substances faster than the system can review and control them.

The United States also continues to face a very significant threat from methamphetamine. Mexican-based cartels import precursor chemicals from Asia on a massive scale and manufacture high purity methamphetamine that is subsequently smuggled into the United States. Seizures along the U.S. Southwest border by U.S. Customs and Border Protection (CBP) have almost doubled between Fiscal Year (FY) 2012 and FY 2015 (from 7,843 kg. to 15,339 kg.). This increase in seizures indicates a rising flow of illicit methamphetamine across our border and into our communities, with California particularly hard hit. The United States is working with the Government of Mexico to detect and destroy methamphetamine manufacturing laboratories, to disrupt smuggling operations, and to prevent precursor chemicals from entering Mexican ports. Current use of methamphetamine in the United States increased 61 percent from 2012 to 2014 (latest data available).[12]

Federal agencies are also working with the Government of China to prevent the diversion of precursor chemicals into the illicit market. This effort includes a growing exchange of information on specific cases being investigated by law enforcement authorities in both countries. ONDCP appreciates the dedicated work by the DEA attaché's office in Beijing to ensure productive cooperation on priority methamphetamine precursor cases. In addition to work in China, U.S. authorities, often through U.S. Pacific Command's Joint Interagency Task Force – West, seek to track and interdict precursor shipments and to disrupt the operations of transnational illicit trafficking networks by bringing key leadership to justice and seizing the illicit proceeds. This work, which also includes extensive efforts by CBP and other interdiction agencies, is a challenging but critical part of our efforts. As is true with all synthetics drugs, because an organic crop in the field cannot be targeted, interdiction requires that focus be made on the key precursor chemicals and the collection and utilization of precise intelligence information.

It is critical that joint U.S.-Mexico enforcement efforts focus on identifying, disrupting and dismantling critical nodes of the cartels' methamphetamine supply chain. Hardening ports of entry and painstaking, intelligence-driven enforcement initiatives can disrupt their manufacturing

[12] 2014 National Survey on Drug Use and Health (NSDUH), HHS/SAMHSA, Sept. 2015

and trafficking operations. We recognize that methamphetamine poses a very serious threat to U.S. citizens and will continue to use every tool at our disposal to address it.

Domestic Actions

Domestic efforts to reduce the availability of NPS should focus on: data collection and research to better understand the scope and consequences of use; enhancing existing prevention and treatment infrastructure; increasing the number of controlled NPS; and improving the scheduling process to make it more responsive to NPS.

Data

Accurate, real time information on a variety of drug measures is crucial to mounting an effective strategy to reduce use and availability of synthetic drugs in the United States. Robust surveillance systems help us understand the scale of the problem and target policies and resources where they can be most effective.

Accurate information about the prevalence of use of synthetic drugs, in particular NPS, in the United States is lacking. Accurately determining use and trends is challenged by the number of identified NPS, the variety of their street names, and the almost infinite number of potential chemical variants of a particular substance.

Over the past several years, Federal agencies have attempted to meet this challenge by adding questions to existing drug data systems and establishing new tools to help fill knowledge gaps. For example, the Monitoring the Future (MTF) study—a survey of 8th, 10th, and 12th grade students supported by the National Institute on Drug Abuse (NIDA) —added questions on past year use of synthetic cannabis among seniors in 2011 and among 8th and 10th graders in 2012. The MTF survey added questions about past year use of synthetic cathinones ("bath salts") among 8th, 10th, and 12th graders in 2012.

In 2013, ONDCP conducted a pilot study to better understand the extent of substance use among criminal justice populations. Through the Community Drug Early Warning System (CDEWS), urine samples from people under the supervision of the criminal justice system (e.g., probation, parole, and drug courts) that were originally collected by the criminal justice program were re-tested by the CDEWS researchers. Typically, the urine samples had been tested by the criminal justice program for only five substances: opioids, cocaine, amphetamines (with confirmation of methamphetamine), cannabis (THC), and PCP. ONDCP supported the CDEWS project to re-test these samples for an expanded panel of drugs, including synthetic cannabinoids. In Phase I of the expanded study, urine samples from over 1,000 subjects from four programs were retested. Results from the study indicated that in the re-test, persons who had initially not tested positive for the five substances were later found to test positive for synthetic cannabinoids. This suggests that some people under the supervision of the criminal justice system may be seeking to avoid detection by use of synthetic cannabinoids.

The study was replicated in 2015 using urine samples from adults and/or juveniles under the supervision of the criminal justice system in three sites. Again, synthetic cannabinoids were found among subjects from all three sites. Moreover, these were typically newer forms of the drugs than had appeared in Phase I. Data analysis from Phase III of the project is currently

underway, with results to be reported by the end of 2016. A fourth phase, which expands the sample to include trauma centers, is currently beginning data collection. The CDEWS results attest to the value of expanded testing protocols to include synthetic drugs and the difficulties inherent in keeping up with the constantly evolving nature of NPS.[13]

The Substance Abuse and Mental Health Services Administration (SAMHSA) continues to fund a number of surveillance efforts to track emerging drug problems such as NPS. In collaboration with the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention (CDC), SAMHSA is implementing the SAMHSA Emergency Department Surveillance Survey, which will replace the Drug Abuse Warning Network by the end of 2016. Data collection began in January 2016. Over the course of the next year, SAMHSA and NCHS will be working with hospitals to identify and track negative consequence of drug use, including NPS, seen in emergency departments. In addition, SAMHSA has established a partnership with the U.S. Department of Agriculture to create the Community Early Warning and Monitoring System. This program builds upon existing collaborations at the regional, state, and local level to improve the gathering, analyses, and sharing of data related to substance use and substance use disorders. More recently, the Association of State and Territorial Health Officials has joined this project to help identify and implement measures to track emerging drug threats such as NPS.

State and local agencies are also working to share emerging testing technologies and best practices, which is providing information about the scope of use and demographics of the population of NPS users. For instance, the Virginia Department of Forensic Science houses a Controlled Substances Section, which tests and reports on state and Federally controlled substances. The Pretrial Services Agency (PSA) for the District of Columbia drug tests individuals on supervised release, probation, or parole. The PSA has partnered with the District's Office of the Chief Medical Examiner (OCME) to develop a testing protocol to increase the capacity for testing samples for NPS. These practices, if more widely adopted, could greatly increase our understanding of the scope of NPS in the United States.

Accurate and timely reporting of overdoses related to synthetic drug use by emergency departments, poison control centers, and medical examiners is also very important to help us understand the prevalence of NPS use and their consequences in the United States. Through monitoring of geographic and temporal overdose clusters, first responders may be better prepared to provide care. In an effort to understand the challenge of treating individuals who have used synthetic drugs, in 2015 the District of Columbia used its emergency rulemaking procedures to require hospitals to collect urine samples from patients who present with symptoms consistent with having taken a synthetic cannabinoid.[14] To maintain anonymity, the OCME removes all personal identifying information from the samples. Through testing of these samples and reports from healthcare providers, officials are learning more about the short- and long-term effects of synthetic drug use and facilitating identification of new substances.

[13]CDEWS-2 report Abstract: https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/finalreport_4_8_15v3.pdf

[14] http://www.dcregs.dc.gov/Gateway/NoticeHome.aspx?NoticeID=5884522

Sustaining critical Federal, state, and local data systems and supporting innovative methods for identifying, tracking, and disseminating knowledge about emerging issues is critical for advancing our efforts to reduce use and availability of NPS.

Research

Research on NPS is very limited. Many of the substances available on the market contain molecules that may or may not share similar risk effects and profiles to the illicit substances they are designed to mimic. As a result, NPS pose serious challenges to researchers and policy-makers that try to assess the risk of harm and to take appropriate measures to control NPS. There are few comprehensive scientific studies on their toxicity and most studies are based on work on animals, fatal poisonings in humans, or clinical observations. Toxicity, abuse liability and risks associated with long-term use in particular remain largely unknown.

NIDA continues to fund research on synthetic cannabinoids, cathinones, and hallucinogens to better understand their pharmacology. This information is used to inform decisions about drug scheduling under the CSA, which requires data about pharmacology, toxicity, and abuse liability, among other factors. Importantly, this research informs prevention and public health responses, including the development of ultra-short acting antagonists that can be used in emergency departments to treat the toxic and sometime deadly effects of NPS.

To further these efforts, in 2012 NIDA also established the Designer Drug Research Unit to disseminate information about the pharmacology and toxicology of newly emerging synthetic drugs. Working with partner organizations, such as the DEA and the Community Epidemiology Work Group, the unit recently determined the molecular mechanism of action for several so-called "bath salts" cathinones.

In addition to better understanding the chemistry and effects of NPS, research is needed to help inform policy responses including: the scale and patterns of NPS use; the relationship between the market for traditionally controlled drugs and NPS; the effectiveness of various control systems; and the effectiveness of current prevention and treatment interventions to prevent and reduce use of NPS.

Prevention

Helping the public understand the known dangers of synthetic drug use is a critical component of preventing use. Federal agencies such as NIDA, SAMHSA, and DEA have developed general public and population specific materials, including fact sheets, web pages, presentations and workshops, to advance understanding of the risks of using synthetic drugs. SAMHSA has developed materials about synthetic cannabinoids for physicians, addiction treatment specialists, and state policy makers.

As suppliers intentionally perpetuate the myth that NPS are "legal highs" that are safe to use because they are available for purchase in stores, providing accurate information about the health harms associated with NPS use is especially important. Truthful and population specific materials on the dangers of NPS are critical to dispel these myths and to protect potential users.

At the community and state level, Federal grants such as the Drug Free Communities (DFC) Support Program, Substance Abuse Prevention and Treatment Block Grant, the Strategic Prevention Framework, the Center for the Application of Prevention Technologies, and even the High Intensity Drug Trafficking Areas (HIDTA) Program are helping to build resilient communities and prevent synthetic drug use by promoting evidence-based prevention practices.

ONDCP administers the DFC Program in collaboration with SAMHSA. The primary purpose of the DFC program is to support community coalitions across the country to prevent and reduce youth substance use and create safer and healthier communities by increasing community collaboration. Recognizing that local problems need local solutions, DFC-funded community coalitions engage multiple sectors of the community and employ a variety of strategies to address local drug problems. Coalition members conduct ongoing community assessments to prioritize efforts to prevent and reduce youth drug use. These assessments are used to plan and implement data-driven, community-wide strategies.

A number of DFC coalitions are helping to reduce use of synthetic drugs. For example, the Franklin Mayor's Drug Task Force in New Hampshire worked with the City of Franklin to adopt the first synthetic cannabinoid ordinance in that state. Also, the North Coastal Prevention Coalition in California has helped identify businesses selling synthetic drugs and has educated the community about the health risks of these drugs.

The HIDTA Program, also administered by ONDCP, targets synthetic drugs as part of its mission. The HIDTA Program 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. The program enhances cooperation among these law enforcement agencies to share information and implement coordinated enforcement activities. In addition to more traditional law enforcement activities, many HIDTA grantees are also engaged in prevention and treatment initiatives. Currently, 27 regional HIDTA programs support prevention initiatives across the country. HIDTA members work with community-based coalitions and adhere to evidence-based prevention practices, such as community mobilization and organizational change.

Recognizing the link between traditional illicit drugs and newly emerging synthetic drugs, several HIDTAs have worked to enhance public education efforts. The following are examples of prevention efforts implemented by HIDTAs that target synthetic drugs:

- The Northwest HIDTA has incorporated information about synthetic cannabinoids into materials and presentations focusing on marijuana and stimulants. The University of Washington's Alcohol and Drug Abuse Institute Clearinghouse acquires and distributes print and electronic materials about synthetic drugs to professionals and the public free of charge.
- The Central Florida HIDTA launched a prevention initiative in 2014 with several DFC-funded coalitions to conduct training and education on synthetic drugs, including hosting two major conferences bringing together law enforcement, education, and medical experts to help address the challenge of synthetic drugs with community stakeholders.

- The Southwest Border HIDTA – South Texas Region works collaboratively with some of the Texas Education Services Regions to provide joint education and prevention classes for students, teachers, and the general public on the health risks of synthetic drugs.

The HIDTA program also supports prevention efforts to reduce the use of methamphetamine. For example, the Southwest Border HIDTA – San Diego/Imperial Region—supports Forces United, a statewide demand reduction project that offers prevention and education activities targeting methamphetamine. All of the California-based HIDTAs (Northern California, Central Valley California, Los Angeles, and the Southwest Border HIDTA – San Diego/Imperial Region) receive services from Forces United, which mobilizes communities and builds collaboration with other prevention associations and coalitions throughout the region.

Other effective efforts taken at the community, municipal, and state level to prevent use of NPS include using licensing, labeling and nuisance abatement statutes as well as banning sales of NPS, Banning sales of NPS also gives officials tools to take stronger actions against businesses selling NPS. In 2015, the District of Columbia, passed emergency legislation to prevent sales of NPS in the District[15] and in April 2016 Mayor Muriel Bowser signed legislation that adds certain classes and substances to the list of Schedule I controlled substances in the District of Columbia Uniform Controlled Substances Act of 1981. The Act, the Revised Synthetics Abatement and Full Enforcement Drug Control Emergency Amendment Act of 2016, is aimed at strengthening officials ability to prosecute cases against sellers and distributors of NPS.[16] At the same time, the District of Columbia increased data collection efforts for NPS. Several other municipalities around the country have also focused law enforcement efforts on reducing retail sales rather than targeting the end user.

Treatment

The Affordable Care Act (ACA) has increased access to mental health and substance use disorders services since it was passed in 2010. The ACA requires coverage for mental health and substance use disorder services by most individual and small employer health insurance plans, including all plans offered through the Health Insurance Marketplace. Building on the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) provisions, the ACA expands mental health and substance use disorder parity protections to an estimated 62 million Americans.[17]

While treatment data on NPS is limited, the CDC has developed information and guidance for clinicians to describe the clinical effects of synthetic cannabinoids, discuss recent clusters of severe disease associated with synthetic cannabinoids, and identify opportunities for clinicians to support surveillance and response efforts.[18] As in the case of other substance use

[15] http://lims.dccouncil.us/Download/34098/B21-0260-SignedAct.pdf
[16] http://lims.dccouncil.us/Download/35385/PR21-0584-Enrollment.pdf
[17] Kirsten Beronio, Rosa Po, Laura Skopec, Sherry Glied. Affordable Care Act Will Expand Mental Health and Substance Use Disorder Benefits and Parity Protections for 62 Million Americans, Feb 2013, Accessed on May 25, 2016: https://aspe.hhs.gov/report/affordable-care-act-expands-mental-health-and-substance-use-disorder-benefits-and-federal-parity-protections-62-million-americans
[18] http://emergency.cdc.gov/coca/ppt/2016/03_31_2016_synthetic_cannnabinoids_coca_call.pdf

disorders, in addition to motivational interventions to help people consider the health risks associated with NPS; to make behavioral changes to moderate or stop drug use; and to prevent relapse, treatment may also need to include health supports and psychosocial therapy.

In 2015, in response to growing concerns about NPS use, the United Kingdom's Home Office released a set of guidelines for educators and frontline practitioners.[19] The guidelines, created by expert group members of NEPTUNE, the Novel Psychoactive Treatment UK Network, were developed to improve clinical practice in the management of use of NPS. Specifically, they aim to improve competence and increase skills of clinicians in the detection, assessment, and management of NPS use in a number of settings including substance use disorder treatment services, emergency rooms, general practice, and sexual health clinics. These guidelines contribute to knowledge about how to most effectively treat NPS use, including acute NPS problems.

Domestic Controls

Authorities under the CSA and the Controlled Substances Analogue Enforcement Act (CSAEA) of 1986, as well as the authority given to the Attorney General by Congress to temporarily place a substance onto Schedule I of the CSA, are aimed at reducing availability of New Psychoactive Substances in the United States.

More recently, the Food and Drug Administration Safety and Innovation Act of 2012, which included the Synthetic Drug Abuse Prevention Act, provided a mechanism for scheduling 5 structural groups of synthetic cannabinoids and placed 26 specific synthetic cannabinoids, synthetic cathinones, and other synthetic substances into Schedule I of the CSA. The Acts also permits DEA to temporarily schedule substances for up to 36 months, which is an increase from 24-month maximum time period for temporary scheduling under the prior law. The changes the Act introduced provided a significant asset to law enforcement; however, drug traffickers quickly regrouped and found ways to circumvent the law by introducing synthetic cannabinoids not covered under the designated structural group. Hence, DEA has had to take emergency action on the most harmful and persistent new synthetic cannabinoids not covered by the law.

Since March 2011, the DEA has used its emergency scheduling authority 10 times to temporarily place 35 substances in Schedule I and most recently in March 2016 completed the temporary control of 2 fentanyl analogs. Because temporarily controlled substances are placed in schedule I, they are subject to the same rules and restrictions under the CSA and Controlled Substances Import and Export Act that apply to other under Schedule I substances, and the manufacture, importation, and sale are subject to the CSA. Federal agencies continue to coordinate a response which includes evaluating these dangerous substances for permanent control under the CSA. Additionally, Congress has responded by controlling 26 synthetic drugs legislatively into Schedule I of the CSA. In addition to the DEA's scheduling efforts, all 50 states and the District of Columbia have adopted legislation to address synthetic drugs, and many have adopted extensive prohibitions against specific compounds or entire classes of compounds.

[19] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/412168/150311_Psychoactive-drugs11-colour_18-33-44_-_1_.pdf

Although scheduling by DEA of more NPS under the existing statutory framework would significantly improve law enforcement capacity to reduce the availability of these substances in the United States, the number of existing NPS and the ability of chemists to manufacture an almost infinite number of them is straining current scheduling tools.

Prosecuting cases under the Analogue statute is resource intensive because of a requirement for additional elements of proof that must be demonstrated to obtain a conviction. In Analogue Act prosecutions, the Government must establish that the substance in question in each case is a "controlled substance analogue" as defined by the CSA; accordingly, each prosecution is a new case even if the same substance is involved.[1] There is no precedent or carry-over from case-to-case or district-to-district, which means prosecutors must start each case anew, a time consuming and resource intensive process.

Although required as part of the process to place new drugs under permanent control, pharmacological data and sufficient scientific knowledge about the substance is often lacking in the case of newly identified NPS, despite the fact that the substance may be nearly identical in its chemical structure to a known controlled substance. While pharmacological testing is neither prohibitively costly nor time-consuming, the sheer volume of new variants makes it impossible for the process to result in the timely control of harmful drugs entering the illicit market.

For the past year, technical experts at DEA, FDA, and NIDA have discussed these issues to determine how the data required to place new drugs under control factors into permanent scheduling processes. A coordinated response to scheduling, balancing public health and public safety, as well as the interests of research and industry, is necessary to help the United States get ahead and stay ahead of the supply of NPS.

In the long term, an examination of more significant reforms to the domestic scheduling framework, taking into account the ever-increasing number of NPS being produced by clandestine manufacturers and the feasibility of attempting to schedule them all by administrative action, is needed to address the threats posed by the substances.

In the meantime, Congress can help by taking an intermediate step to control a large number of structurally related New Psychoactive Substances.

Recognizing NPS as an evolving challenge, a number of countries have recently taken bold steps aimed specifically at reducing availability of these dangerous drugs. Australia, for example, passed legislation in September 2015 that permits the Australian Border Force to conduct a seizure without a warrant as long as it has a reasonable suspicion that the product is either a psychoactive substance or made to mimic the effect of an illegal drug. The new law, the Crimes Legislation Amendment, places the burden on importers to prove the synthetic drug has a legitimate use.

The United Kingdom also recently enacted legislation on NPS. On May 26, 2016, the Psychoactive Substances Act took effect and restricts the production, sale, and supply of any substance capable of producing a psychoactive effect. The Act eliminates the need to study and

classify each newly emerging substance. This Act does not preclude using the chemicals for approved healthcare activities and approved scientific research[20].

ONDCP will continue to communicate with the International Narcotics Control Board, Global Smart, and with its counterparts in Australia, the United Kingdom, and other nations to gather best practices that can inform responses to NPS.

Conclusion

While ONDCP and Federal partners have worked to reduce availability and use of synthetic drugs, much remains to be done. We have gaps in our ability to track prevalence trends, making it hard to determine where to devote resources. There is also a need for training additional healthcare practitioners to identify and address substance use disorders. Healthcare practitioners lack access to assessment and treatment resources to identify and treat synthetic drug overdoses. Treatment protocols currently focus on the symptoms presented rather than on the substance causing the overdose. There is a research gap on how NPS act on the brain. Without this information, we cannot focus prevention and treatment efforts, including the development of antagonists to reverse overdoses. Finally, our scheduling system cannot keep up with the volume of NPS on the market. International partners such as China could take additional domestic actions to help reduce the availability of precursor chemicals and NPS. Mexico could intensify their efforts to identify and destroy methamphetamine laboratories.

ONDCP will continue to work with our international partners, Federal Government Departments and Agencies, and our partners at the state, local and tribal levels to address these problem areas and to prevent the tragic effect these dangerous drugs are having in our communities.

Thank you for the opportunity to testify today and for your commitment to this important issue.

[20] http://www.legislation.gov.uk/ukpga/2016/2/contents/enacted