

PRESCRIBING CONTROLLED SUBSTANCES: THE POTENTIAL OF ABUSE AND NON-COMPLIANCE

Wisconsin Worker's Compensation Forum

October 6th, 2021

DISCLAIMER

This presentation and materials are for general compliance education only, and the information provided does not constitute medical or legal advice to any person.

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- **Drug Education Consulting Group**

- Educate corporate/private groups on drug trafficking and its impact on society

- **25 years as Special Agent with the DEA (Retired in 2008)**

- Served Assignments in Atlanta, Denver, El Paso, Los Angeles and Thailand
- Investigated global drug trafficking organizations
- Served in Washington, D.C. as Chief of DEA's International Intelligence Program

- **10 Years as a Police Officer in Cobb County, Georgia**

- Served on multi-agency narcotics unit investigating regional and local narcotics issues, including diversion of prescription drugs
- Conducted numerous undercover assignments; taught undercover techniques at police academies.

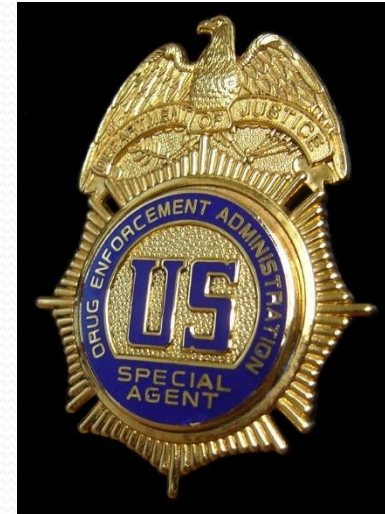
KEY TOPICS

- **Understanding prescription drug abuse and non-compliance**
- **Recognizing aberrant patient behaviors and how these behaviors may be symptomatic of non-compliance**
- **Methods for detecting non-compliant patient behavior**
- **Monitoring patient adherence to a prescription regimen**
- **Key government initiatives aimed at prescription abuse and specific duties of DEA**

DEA Mission

To prevent, detect, and investigate the diversion of controlled substances from legitimate sources

while



Ensuring an adequate and uninterrupted supply for legitimate medical and scientific purposes.



U.S. Department of Justice Drug Enforcement Administration
Office of Diversion Control

CLOSED SYSTEM OF DISTRIBUTION

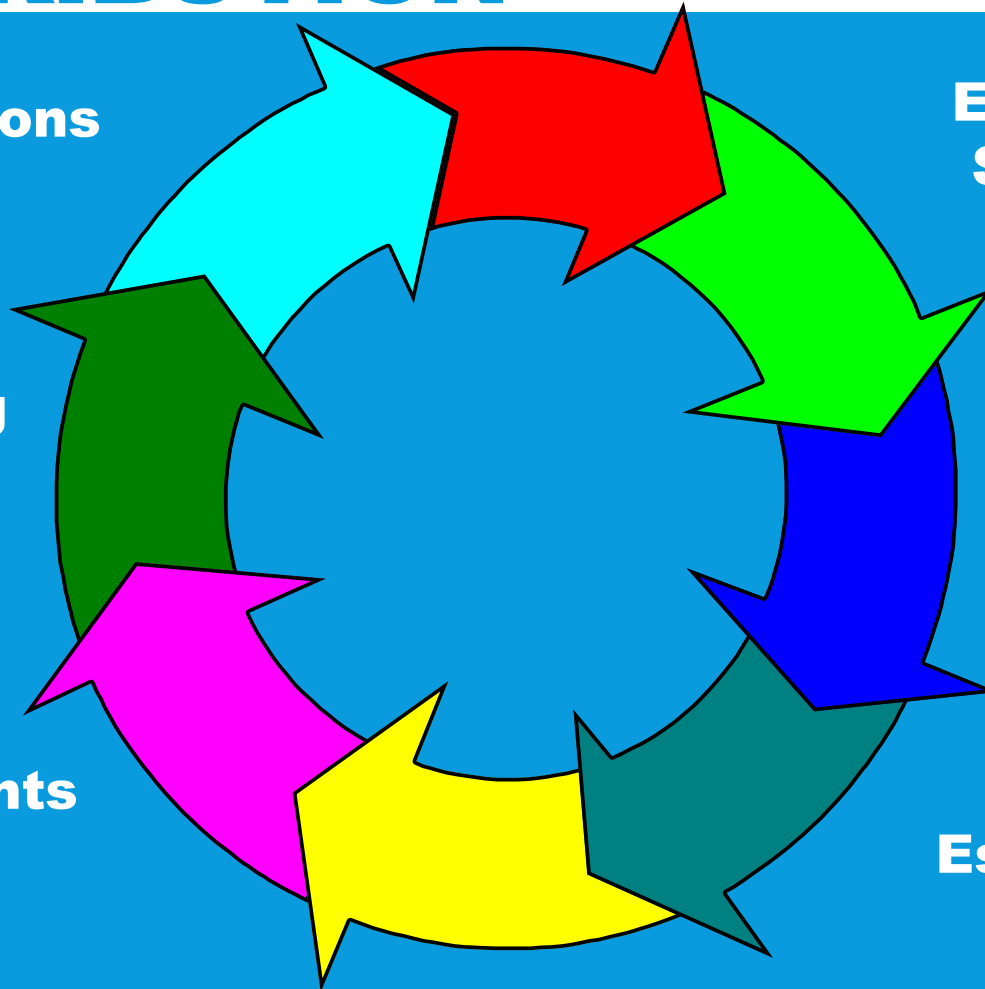
Investigations

Established Schedules

Registration

Established Quotas

ARCOS



Record Keeping Requirements

Security Requirements

WHAT IS YOUR RESPONSIBILITY?

There is a responsibility to:

- **Assure patients are using medications properly.**
- **If aberrant behavior is observed, noted in testing or received via a complaint to the practice ...**

... Do not ignore it.

TWO DIMENSIONS OF THE PROBLEM

**Illicit use or abuse of
prescription medications**

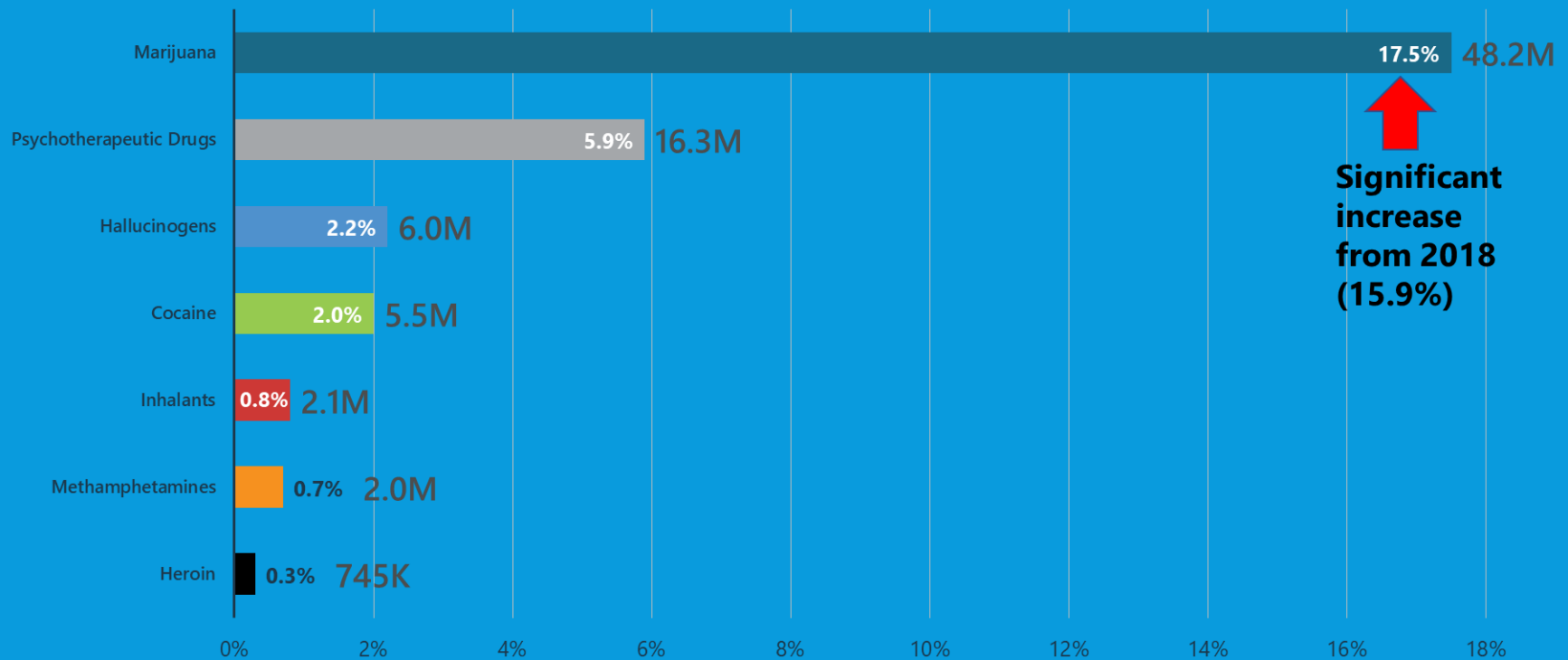
**Non-compliance with
prescription regimens**

Illicit Use Of Prescription Medications

Targeting the Drug Seeking Patient

Illicit Drug Use: Major Concerns: Opioids, Marijuana, Methamphetamines

PAST YEAR, 2019 NSDUH, 12+



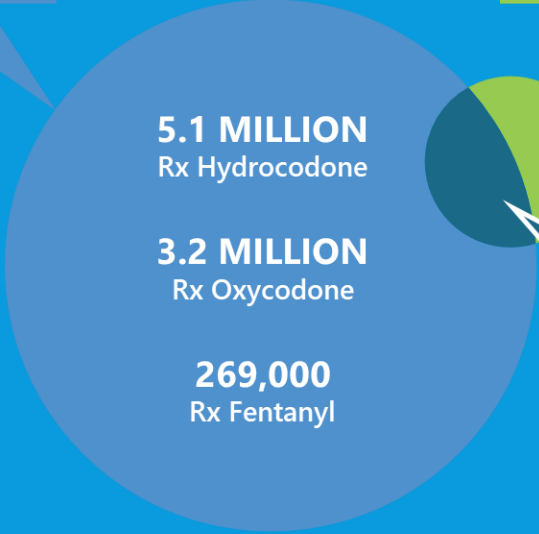
PROGRESS ON THE OPIOID EPIDEMIC: PRESCRIPTION PAIN RELIEVER MISUSE

PAST YEAR, 2019 NSDUH, 12+

10.1 MILLION PEOPLE WITH OPIOID MISUSE (3.7% OF TOTAL POPULATION)

9.7 MILLION
Rx Pain Reliever Misusers
(96.6% of opioid misusers)

745,000
Heroin Users
(7.4% of opioid misusers)



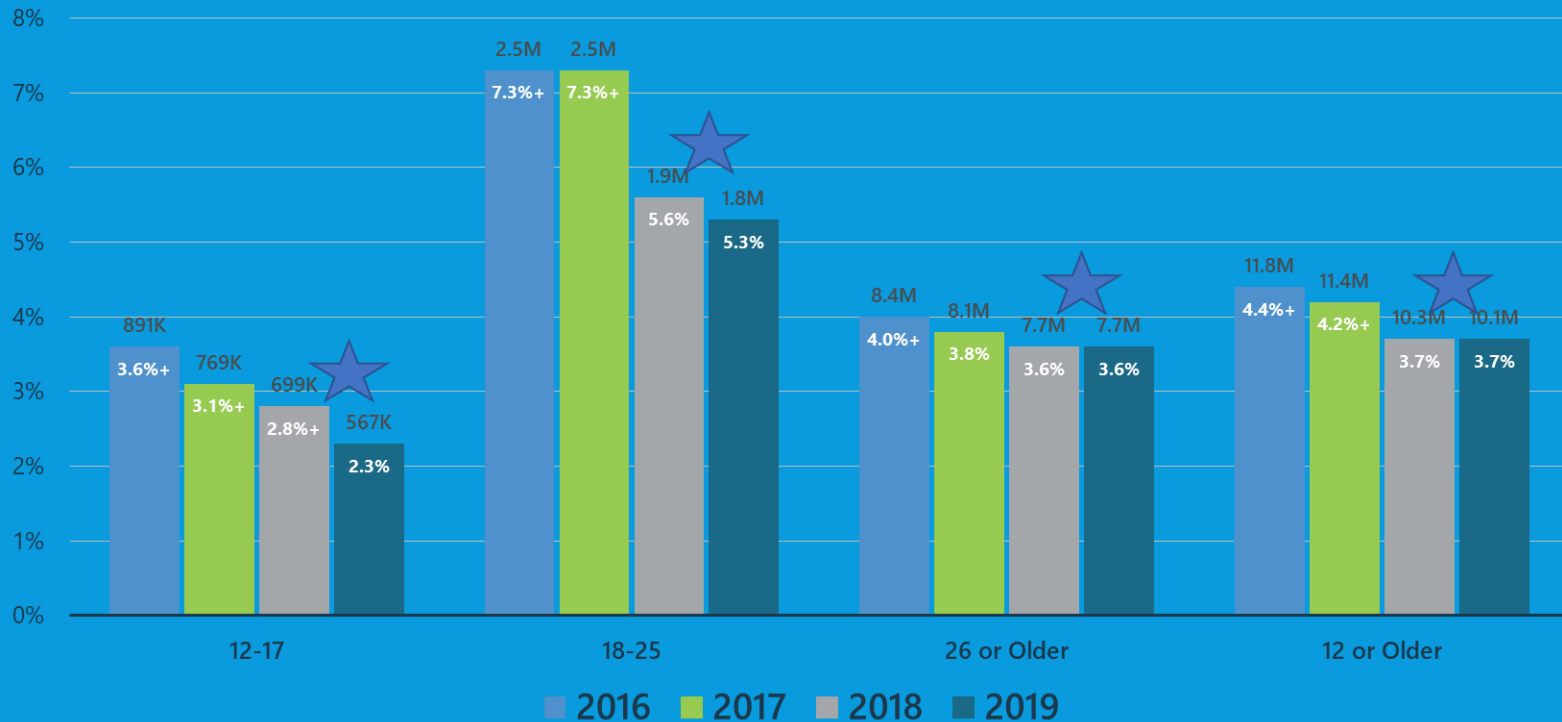
Modest decline overall for each opioid category except prescribed fentanyl (no change)

404,000
Rx Pain Reliever Misusers and Heroin Users
(4.0% of opioid misusers)

Rx = prescription.
Opioid misuse is defined as heroin use or prescription pain reliever misuse.

Opioid Misuse

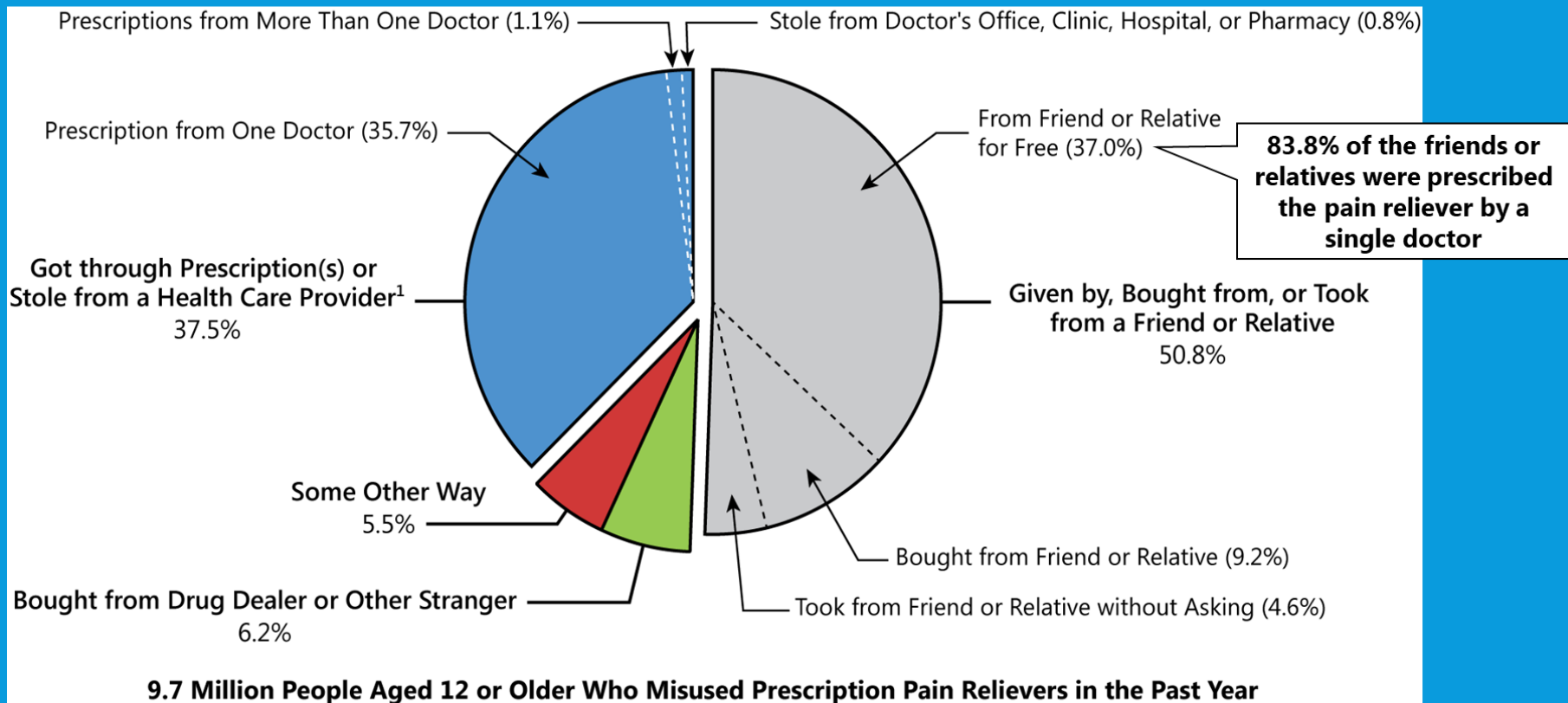
PAST YEAR, 2016-2019 NSDUH, 12+



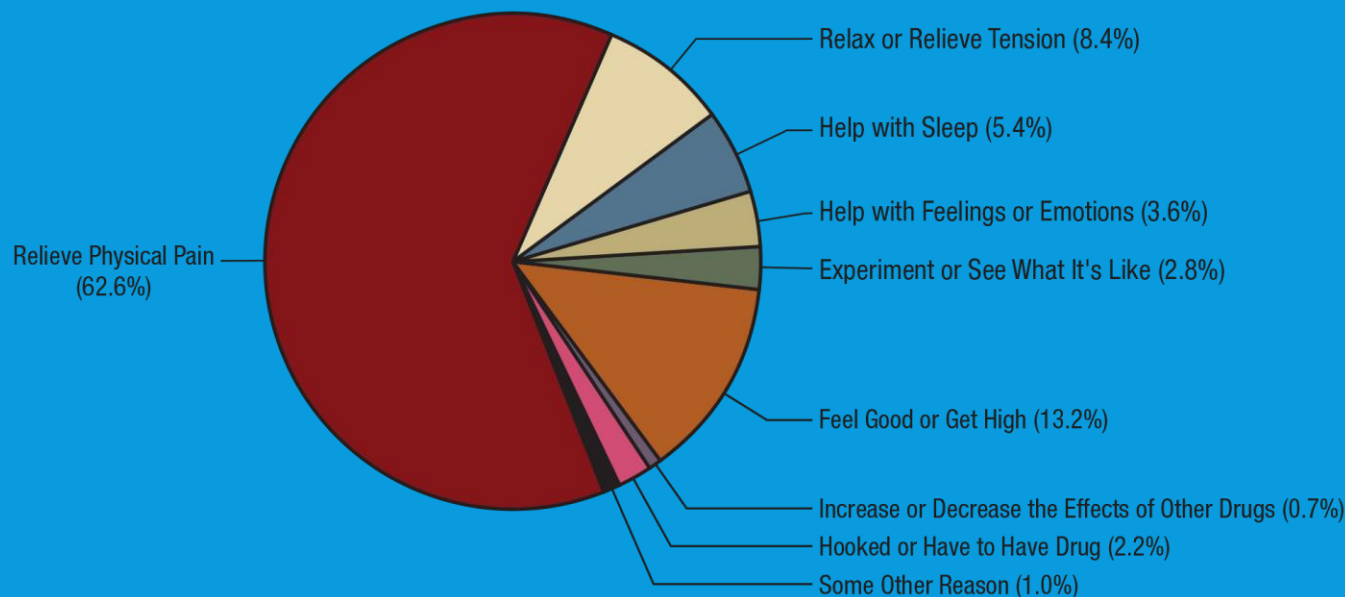
+ Difference between this estimate and the 2019 estimate is statistically significant at the .05 level.

Source Where Pain Relievers Were Obtained for Most Recent Misuse among People Aged 12 or Older Who Misused Pain Relievers in the Past Year: 2019

PAST YEAR, 2019 NSDUH, 12+



MAIN REASON FOR THE MOST RECENT PRESCRIPTION PAIN RELIEVER MISUSE AMONG PEOPLE AGED 12 OR OLDER WHO MISUSED PRESCRIPTION PAIN RELIEVERS IN THE PAST YEAR: PERCENTAGES, 2017



11.1 Million People Aged 12 or Older Who Misused Prescription Pain Relievers in the Past Year

<https://www.samhsa.gov/data/report/slides-2017-nsduh-annual-national-report>

Note: The percentages do not add to 100 percent due to rounding.

THE PRESCRIPTION DRUG ABUSER, SOME COMMON CHARACTERISTICS (BUT NOT LIMITED TO)

- Unusual behavior in the waiting room
- Assertive personality
 - Often demanding immediate action
- Unusual appearance
 - Extremes of slovenliness or being overdressed
- Unusual knowledge of controlled substances
- Recites medical history with textbook symptoms
- Evasive or vague answers to questions regarding medical history

THE PRESCRIPTION DRUG ABUSER, SOME COMMON CHARACTERISTICS (BUT NOT LIMITED TO)

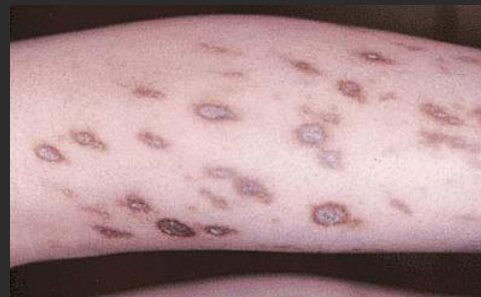
- Reluctant or unwilling to provide reference information
 - Often has no regular doctor or health insurance
- May request a specific medication and may be reluctant to try a different drug
- May appear to have no interest in diagnosis
 - Fails to keep appointments for further diagnostic tests; refuses to see another practitioner for consultation

RECOGNIZING THE PHYSICAL SIGNS OF PRESCRIPTION DRUG ABUSE

Abusers of prescription drugs may use or ingest prescription medication in the same manner as abusers of illicit drugs, yielding the same signs of illicit use.

Signs of illicit use:

- Inflammation in nasal cavity
- Gum disease and infection
- Signs of subcutaneous use
 - Between toes
 - Under tongue
 - Behind knees
 - Genitalia
 - Arms



OTHER EVIDENCE OF POSSIBLE PRESCRIPTION DRUG ABUSE

- **Information gained from the urine drug testing**
- **Information received from sources other than the patient:**
 - **Other practices or pharmacies**
 - **Friends or family**
 - **Anonymous sources**

DEA'S ROLE IN PRESCRIBING CONTROLLED SUBSTANCES

- ▶ DEA's role under the Controlled Substances Act (CSA) is to ensure that controlled substances are prescribed, administered, and dispensed only for **legitimate medical purposes** by DEA-registered practitioners acting in the usual course of professional practice and otherwise in accordance with the CSA and DEA regulations. Each State also has its own laws (administered by State agencies) requiring that a prescription for a controlled substance be issued only for a legitimate medical purpose by State-licensed practitioners acting in the usual course of professional practice.

LEGITIMATE MEDICAL PURPOSE USUAL COURSE OF PROFESSIONAL PRACTICE

This requirement has been construed by the courts to mean that the Rx must be issued “in accordance with a standard of medical practice generally recognized and accepted in the United States.”

United States v. Moore
423 U.S. 122 (1975)

Non-compliance With Prescription Regimens



Not all non-compliant patients are abusers

POSSIBLE NON-COMPLIANCE SCENARIOS

- Is the patient taking drugs as prescribed?**
- Is the patient sharing his or her medications with others?**
- Does the patient take a smaller than prescribed dose?**
- Is the patient hoarding medication?**

MONITORING FOR ABUSE AND NON-COMPLIANCE

- Practices should periodically assess all patients using controlled substances for a prolonged period of time.
- Assessment approaches can include:
 - **Assessment of patient progress toward achieving therapeutic goals**
 - **Presence of adverse events**
 - **When indicated because a patient is high risk or is known to have engaged in aberrant behavior, results of urine drug testing**
 - Adherence to prescribed therapies
 - Standardized screening tools to assess for:
 - **Aberrant drug-related behaviors**
 - **Substance abuse**
 - **Psychological issues**

SUGGESTED PATIENT ASSESSMENT QUESTIONS

- Has the patient ever sought treatment for drug abuse?
- Is the patient seeing more than one physician?
- Is the patient comfortable with a detailed pain management agreement if they are using controlled substances for a prolonged period of time?
- Is the patient comfortable with periodic urine drug testing?
- Is the patient using illicit drug(s)?
 - Does the patient have physical signs of drug abuse?

The initial interview can set the tone for further discussion and use of risk management tools.

RISK ASSESSMENT: AN *ONGOING PROCESS*

- **Be aware of pill counts**
- **Consider caregivers, friends and family for potential of diverting or misusing medications**
- **Have a medication agreement with the patient that includes expectations of the treatment plan**
- **Use of a prescription monitoring solution, as a tool to assist the physician, in assessment of patient adherence to prescribed regimens**

THE MORE YOU KNOW, THE BETTER

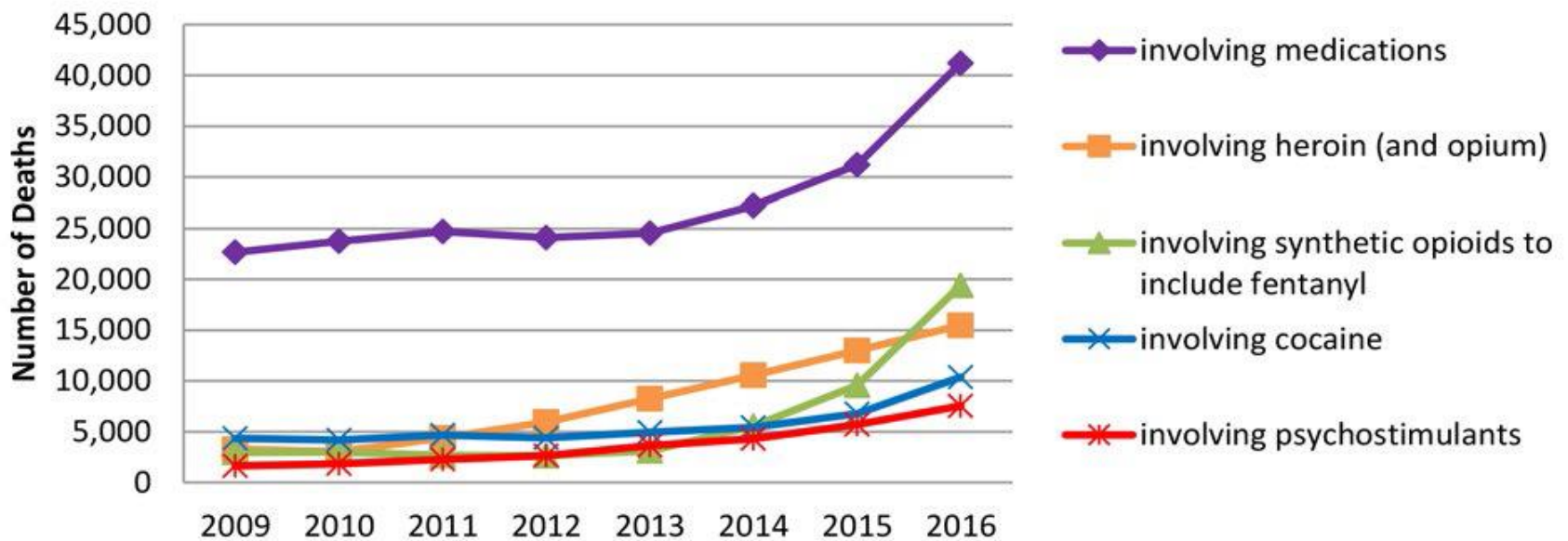
Physicians should know the following:

- Whether patients are likely to be taking their medications in a manner consistent with the dose and frequency prescribed?
- Is a patient taking illicit drugs?
- Is a pain medication present at high concentrations, which could indicate abuse?
 - Can those levels be shown in a prescription monitoring report?
- Is the prescribed medication not present?
 - Could indicate non-compliance or possible diversion.

What About Patient Charts ?

- Patient files and charts should be complete and accurate, clearly legible, fully articulate and document each patient medical history, a thorough physical examination conducted, medical diagnosis and justification for writing any controlled substance prescription being issued to a patient for **a legitimate medical purpose** as well as any authorization for refills.
- The files and charts should be absent of red flags that will require further investigation by DEA.
- When appropriate files and charts should include results of blood work, electronic imaging such as: x-rays, scans and/or MRI testing, additional physician consults and opinions and your follow-up with the patient. Some doctors have included the results of random urinalysis drug screening for patients who regularly receive controlled substance prescriptions to assure they are legitimately using the medication and not diverting the drugs.

DRUG OVERDOSE DEATHS INVOLVING SELECTED DRUGS, 2009-2016



THE PART FENTANYL PLAYS IN OVERDOSE DEATHS

- Sharp increases in opioid overdose deaths since 2013 are partly explained by the introduction of illicitly manufactured fentanyl into the heroin market. Outbreaks related to fentanyl analogs also have occurred. One fentanyl analog, Carfentanil, is estimated to be 10,000 times more potent than morphine. Fentanyl analogs are not routinely detected because specialized toxicology testing is required.
- Illicitly manufactured fentanyl is now a major driver of opioid overdose deaths in multiple states, with a variety of fentanyl analogs increasingly involved, if not solely implicated, in these deaths. This finding raises concern that in the near future, fentanyl analog overdose deaths might mirror the rapidly rising trajectory of fentanyl overdose deaths that began in 2013 and become a major factor in opioid overdose deaths.

• O'Donnell JK, Halpin J, Mattson CL, Goldberger BA, Gladden RM. Deaths Involving Fentanyl, Fentanyl Analogs, and U-47700 — 10 States, July–December 2016. MMWR Morb Mortal Wkly Rep 2017;66:1197–1202. DOI: <http://dx.doi.org/10.15585/mmwr.mm6643e1>.

RESOURCES



<https://www.deadiversion.usdoj.gov/>



<https://www.samhsa.gov/ebp-substances/opioids>

<https://www.whitehouse.gov/ondcp/>



ILLICIT USE PEER REVIEW WEBSITES



<http://www.bluelight.org/vb/content/>

- Peer Reports on the use of various opiates
- Non-scientific data on uses of various opiates
- Data from the “user” perspective

streetRx

Inspired by the principles of crowdsourcing, StreetRx is a one-of-a-kind program that identifies and tracks the street value of prescription and illicit drugs. StreetRx gathers user-submitted data to map the street price of a variety of drugs across the country.

StreetRx users can anonymously post, view, and rate submissions, shedding new light onto the often muddy waters of the black market. By providing invaluable information about the preferences of users, health communication specialists can adapt the outreach efforts to the local needs of their community.

PROTECTING PRESCRIBERS , CONCERNED PARTIES AND APPROPRIATELY TREATING PATIENTS

- This program is NOT intended to discourage the prescribing or dispensing of appropriate medication for legitimate medical purposes.
- **Physicians and other authorized prescribers and concerned parties should not allow those who divert or misuse prescription drugs to influence the legitimate prescribing and dispensing of controlled substances.**

NEW PSYCHOACTIVE SUBSTANCES (NPS)

- New Psychoactive Substances (NPSs) are a diverse group of synthetic substances that are purported to have similar effects to controlled substances. The NPS market is typified by new substances constantly being created and marketed to users, most often as legal alternatives to controlled substances. Synthetic cannabinoids and synthetic cathinones are the most common classes of NPSs available and abused in the United States; however, there are many other classes of NPSs including opioids, phenethylamines, tryptamines, benzodiazepines, and piperazines. Synthetic cannabinoids are commonly applied to plant material or suspended in an oil and are designed to be smoked or used in e-cigarettes. Synthetic cathinones are usually powder or crystal substances, typically consumed in powder, tablet, or capsule form. In addition to these classes of NPSs, designer benzodiazepines and synthetic opioids garnered significant national attention in 2019 for their presence in overdoses and deaths.

<https://www.dea.gov/documents/2021/03/02/2020-national-drug-threat-assessment>

Isotonitazene [Iso]

Isotonitazene is chemically known as, N,N-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine.

Isotonitazene is a potent synthetic opioid, and it is being abused for its opioidergic effects. The abuse of isotonitazene, similar to other [synthetic opioids](#), has been associated with adverse health effects, including numerous deaths.

Law enforcement data indicate that isotonitazene has appeared in the United States illicit drug market. Law enforcement has encountered isotonitazene primarily in powder form.

Isotonitazene is not an approved pharmaceutical product and is not approved for medical use anywhere in the world. [DEA](#) has issued a temporary order placing isotonitazene into Schedule I of the [CSA](#) (85 FR 51342). Prior to the temporary order, under 21 U.S.C. § 802 (32)(A), isotonitazene can be treated as an analogue of [etonitazene](#), a schedule I substance.

Related Articles

- [Technical Report on Isotonitazene \(EMCDDA\)](#)

The purpose of this technical report is to provide an analysis of the available information on N,N-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1H-benzimidazole-1-ethanamine (commonly known as isotonitazene), an opioid analgesic that has recently emerged on the drug market in Europe, to support a risk assessment of the substance that has been requested by the European Commission in accordance with Article 5c of Regulation (EC) No 1920/2006 (as amended).

ISOTONITAZENE

https://www.deadiversion.usdoj.gov/drug_chem_info/isotonitazene.pdf

FLUALPRAZOLAM (Street Name: Flualp)

August 2019
DEA/DC/DO/DOE

Introduction

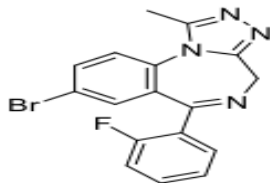
Flubromazolam is a triazole analogue of the designer benzodiazepine, flubromazepam. As a class of drugs, benzodiazepines produce central nervous system (CNS) depression and are commonly used to treat, panic disorders, anxiety and insomnia. The United States Food and Drug Administration has not approved Flubromazolam for therapeutic use.

Licit Uses

Flubromazolam does not currently have an accepted medical use in the United States.

Chemistry

Flubromazolam (8-bromo-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine) is a triazole analogue of the benzodiazepine flubromazepam. Flubromazolam is composed of a benzene ring fused to a seven-membered 1,4-diazepine ring that is also fused to a 1,2,4 triazole ring. An alkyl methyl (-CH₃) is attached at the 1-position of the triazole ring, a 2-fluorophenyl ring is attached at the 6-position of the diazepine ring, and a bromine is attached at the 8-position of the benzene ring. Flubromazolam has a molecular formula of C₁₇H₁₂BrFN₄ and a molecular weight of 371.21 g/mol. The structure of flubromazolam is shown below:



Pharmacology

Flubromazolam, similar to schedule IV benzodiazepines (such as alprazolam, clonazepam, diazepam), binds to the benzodiazepine receptors with high affinity and efficacy. Flubromazolam possesses central nervous system depressant effects, such as anxiolytic, anticonvulsant, sedative-hypnotic and muscle relaxant effects. The recreational use of flubromazolam may result in prolonged, severe intoxication associated with coma, hypotension, and rhabdomyolysis (a breakdown of muscle tissue leading to release of dangerous protein into the bloodstream).

According to a published case report in which a 44 year-old investigator (weighing 75 kg) orally ingested a low dose

(0.5 mg/day) of flubromazolam, sedative-hypnotic effects as well as muscle relaxant effects occurred 90 minutes following drug intake. Drowsiness occurred approximately three hours post-drug ingestion, and lasted for five hours. Intoxication due to flubromazolam is characterized by excessive drowsiness, partial amnesia and inability to follow or participate in conversation. Peak serum concentration of flubromazolam is reached approximately 5 hours (7.4 ng/mL) after administration with a second peak occurring after 8 hours (8.6 ng/mL), making it a long-acting benzodiazepine. In a single-dose pharmacokinetic study in humans, 30 hours following flubromazolam ingestion, a re-emergence of sedative effects was observed.

User Population

Flubromazolam is used as a recreational substance in the United States. It is abused by a broad range of groups including youths, young adults, and older adults.

Illicit Distribution

Flubromazolam can be purchased via the internet and at local retail shops. It has been identified in PEZ-like pills or tablets. The National Forensic Laboratory Information System (NFLIS) is a DEA database that collects scientifically verified data on drug items and cases submitted to and analyzed by state, local, and federal forensic laboratories. According to NFLIS, the number of flubromazolam drug reports increased from 14 in 2015 to 27 in 2016 and, has continued to increase to 261 in 2017. In 2018, there were 398 reports of flubromazolam in the NFLIS database.

The National Poison Data System (NPDS) of the American Association of Poison Control Centers (AAPCC) by members of the public and health care providers reported no flubromazolam single substance exposures in 2014 and 2015, 2 exposures in 2016 and 11 in 2017. In 2017, the UNODC Early Warning Advisory on Novel Psychoactive Substances mentioned flubromazolam in its report.

Control Status

Flubromazolam is not currently controlled under the Controlled Substances Act.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section; Fax 202-353-1263, telephone 202-307-7183, and Email DPE@usdoj.gov.

SUMMARY

- Prescription drug abuse and non-compliance should be a critical concern for all practices.
- Be aware of aberrant patient behaviors.
- Monitoring for non-compliance and controlled substance abuse is a continuous, ongoing process. Urine drug testing should only be ordered from an independent laboratory when the medical provider deems the testing to be medically necessary for patient treatment purposes.
- Ensuring adherence to a prescription regimen is crucial for protecting patient safety and society at large.

DISCLAIMER

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