FDA Drug Safety Communication

FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions

Serious risks with misuse, abuse, addiction, and sharing these drugs

05-11-2023 FDA Drug Safety Communication

What safety concern is FDA announcing?

To address continuing concerns of misuse, abuse, addiction, and overdose of prescription stimulants, the U.S. Food and Drug Administration (FDA) is requiring updates to the *Boxed Warning* and other information to ensure the prescribing information is made consistent across the entire class of these medicines. The current prescribing information for some prescription stimulants does not provide up to date warnings about the harms of misuse and abuse, and particularly that most individuals who misuse prescription stimulants get their drugs from other family members or peers. Further, individuals who are prescribed stimulants are often faced with requests to share their medication. Sharing these medicines with others can lead to development of substance use disorder and addiction in those with whom these drugs are shared.

Prescription stimulants can be an important treatment option for disorders for which they are indicated. However, even when prescribed to treat an indicated disorder, their use can lead to misuse or abuse. Misuse and abuse, also called nonmedical use, can include taking your own medicine differently than prescribed or using someone else's medicine. For this reason, sharing prescription stimulants with those for whom they are not prescribed is an important concern and a major contributor to nonmedical use and addiction. Misuse and abuse of prescription stimulants can result in overdose and death, and this risk is increased with higher doses or unapproved methods of taking the medicine such as snorting or injecting.

What is FDA doing?

We are requiring the *Boxed Warning*, FDA's most prominent warning, to be updated and we are adding other information to the prescribing information for all prescription stimulants. We are adding information that patients should never share their prescription stimulants with anyone, and the *Boxed Warning* information will describe the risks of misuse, abuse, addiction, and overdose consistently across all medicines in the class. The *Boxed Warning* also will advise heath care professionals to monitor patients closely for signs and symptoms of misuse, abuse, and addiction.

Information on these risks is being required in several sections of the prescribing information, including the *Warnings and Precautions*, *Drug Abuse and Dependence*, *Overdosage*, and *Patient Counseling* sections. We are also requiring updates to the existing patient Medication Guides to help educate patients and caregivers about these risks.

What is a prescription stimulant and how can it help me?

Prescription stimulants are used to treat attention deficit/hyperactivity disorder (ADHD), binge-eating disorder, and uncontrollable episodes of deep sleep called narcolepsy. Prescription stimulants may help decrease impulsivity and hyperactivity, and increase attention in patients with ADHD; help reduce the number of excessive overeating episodes in patients with binge-eating disorder; and help promote wakefulness in patients with narcolepsy. These medicines have benefits when used appropriately, but

they also have serious risks, including the risk of misuse and abuse, addiction, overdose, and death. Examples of common prescription stimulants include Adderall (amphetamine/dextroamphetamine), Concerta (methylphenidate), Dexedrine (dextroamphetamine), and Ritalin (methylphenidate).

What should health care professionals do?
Assess patient risk of misuse, abuse, and addiction before prescribing stimulant medicines. Counsel patients not to share their prescribed stimulant with anyone else. Educate patients and their families on these serious risks, proper storage of the medicine, and proper disposal of any unused medicine. Throughout treatment, regularly assess and monitor them for signs and symptoms of nonmedical use, addiction, and potential diversion, which may be evidenced by more frequent renewal requests than warranted by the prescribed dosage.

What should patients and caregivers do?
Always take your prescription stimulant exactly as prescribed by your health care professional. Do not take more of the medicine or take it more often than prescribed. Never provide any of your prescription stimulant medicine to anyone else as it can have serious risks for those for whom it was not prescribed. Store your prescription stimulant medicines securely, out of sight and reach of children and in a location not accessible by others, including visitors to the home. Immediately dispose of unused or expired prescription stimulants properly or take them to a drug take-back site, location, or program. Talk to your health care professional if your use of prescription stimulants has resulted in problems with your health, relationships, responsibilities, or the law, or if you are struggling with misusing these or other medicines. Go to an emergency room or call 911 if you experience symptoms of stimulant overdose, including new tremors or change in existing tremors, seizures, restless or aggressive behavior, overactive reflexes, fast breathing, fast or irregular pulse rate, confusion, stomach cramps, or more serious symptoms such as heart attack or stroke. Talk to your health care professional if you have questions or concerns about risks of taking prescription stimulants.

What did FDA find?
We reviewed the medical literature published from January 2006 to May 2020 on misuse and abuse, also called nonmedical use, of prescription stimulants and associated adverse events. Overall, the most common source of prescription stimulants for nonmedical use in the general population came from friends or family members, with estimates generally ranging from 56 percent to 80 percent, usually provided for free. Nonmedical use from their own prescription accounted for approximately 10 percent to 20 percent of people who report having used stimulants nonmedically in the past year. Less commonly reported sources included drug dealers or strangers accounting for 4 percent to 7 percent of people who report having used stimulants nonmedically in the past year, and the internet accounting for 1 percent to 2 percent.

Our review found that nonmedical use has remained relatively stable over the past two decades, despite the increasing number of prescription stimulants dispensed. However, the past-year prevalence of nonmedical use of these medicines varies across specific subpopulations and is highest in the following groups: young adults ages 18 to 25 (estimates ranged from 4.1 percent to 7.5 percent), college students (4.3 percent), and adolescents and young adults diagnosed with ADHD (estimates ranged from 14 percent to 32 percent). According to the available data, people who use prescription stimulants for nonmedical reasons have a higher risk of developing a substance use disorder than those who do not. The most serious harms were more commonly observed with nonmedical use by a non-oral route such

as snorting or injecting.

What is my risk?
All medicines have side effects even when used correctly as prescribed. It is important to know that people respond differently to all medicines depending on their health, the diseases they have, genetic factors, other medicines they are taking, and many other factors. As a result, we cannot determine how likely it is that someone will experience these side effects when taking prescription stimulants. However, it is harmful to take prescription stimulants or other medicines in ways other than exactly as prescribed by your health care professional. Talk to your health care professional if you have questions or concerns about the risks of taking prescription stimulant medicines.

How do I report side effects from prescription stimulants?
To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving prescription stimulants or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

How can I get new safety information on medicines I'm prescribing or taking?
You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Table of Prescription Stimulant Label changes
The following tables provide comparisons of the more significant updates FDA is requiring to ensure that the prescribing information concerning the serious risks of misuse, abuse, addiction, and sharing of these medications with those for whom they are not prescribed is consistent across the entire class of prescription stimulant medicines. These updates will align labels with recent labeling language, address diversion and stigmatization, and incorporate recent safety changes.
The "Former" column contains current language, with removals shown by red-lined text. The "New" column shows updated language in **bold in the "New" column** and will be added to the Boxed Warning (Table 1), Warnings and Precautions (Table 2), Drug Abuse and Dependence (Table 3), Overdosage (Table 4), and Patient Counseling Information (Table 5).

*NOTE: There are different versions of the example language across the stimulant class. Other minor updates were incorporated within this action but are not listed below and will be available once the label updates for each product are approved by FDA.

Table 1. Boxed Warning	
Former*	**New**
~~POTENTIAL for~~ ABUSE ~~AND DEPENDENCE~~ ~~CNS stimulants, including~~ [DRUG-X]~~, other amphetamine-containing products, and methylphenidate,~~ have high potential for abuse ~~and dependence~~. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy [see WARNING AND PRECAUTIONS (5.1) and DRUG ABUSE AND DEPENDENCE (9.2, 9.3)].	WARNING: ABUSE**, MISUSE, AND ADDICTION** DRUG-X has a high potential for abuse **and misuse,** which can lead to the development of a substance use disorder, including addiction. **Misuse and abuse of CNS stimulants, including DRUG-X, can result in overdose and death [see Overdosage (10)], and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.** **Before prescribing DRUG-X,** assess each patient's

	risk for abuse**, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout DRUG-X treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction [see Warnings and Precautions (5.1) and Drug Abuse and Dependence (9.2)].**
Table 2. Warnings and Precautions	
Former*	**New**
~~**Potential for Abuse and Dependence**~~ ~~CNS stimulants, including DRUG-X, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy [see Boxed Warning, Drug Abuse and Dependence (9.2, 9.3)].~~	**Abuse, Misuse, and Addiction** DRUG-X has a high potential for abuse **and misuse. The use of DRUG-X exposes individuals to the risks of abuse and misuse, which can lead to the development of a substance use disorder, including addiction. DRUG-X can be diverted for non-medical use into illicit channels or distribution [see Drug Abuse and Dependence (9.2)]. Misuse and abuse of CNS stimulants, including DRUG-X, can result in overdose and death [see Overdosage (10)], and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.** **Before prescribing DRUG-X,** assess each patient's risk for abuse**, misuse, and addiction. Educate patients and their families about these risks and proper disposal of any unused drug. Advise patients to store DRUG-X in a safe place, preferably locked, and instruct patients to not give DRUG-X to anyone else. Throughout DRUG-X treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently** monitor for signs **and symptoms of** abuse**, misuse, and addiction.**
Table 3. Drug Abuse and Dependence	
Former*	**New**
~~CNS stimulants, including~~ DRUG-X~~, other amphetamines, and methylphenidate-containing products~~ have a high potential for abuse. Abuse is the intentional non-therapeutic use of a drug, even once, to achieve a desired psychological or physiological effect. Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use (e.g., continuing drug use despite harmful consequences, giving a higher priority to drug use than other activities and obligations), and possible tolerance or physical dependence. ~~Both abuse and misuse may lead to addiction, and some individuals may develop addiction even when taking [DRUG-X] as prescribed.~~	DRUG-X has a high potential for abuse **and misuse which can lead to the development of a substance use disorder, including addiction [see Warnings and Precautions (5.1)]. DRUG-X can be diverted for non-medical use into illicit channels or distribution.** Abuse is the intentional non-therapeutic use of a drug, even once, to achieve a desired psychological or physiological effect. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed. Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use (e.g.,

~~Signs and symptoms of CNS stimulant abuse may include increased heart rate, respiratory rate, blood pressure, and/or sweating, dilated pupils, hyperactivity, restlessness, insomnia, decreased appetite, loss of coordination, tremors, flushed skin, vomiting, and/or abdominal pain. Anxiety, psychosis, hostility, aggression, and suicidal or homicidal ideation have also been observed. Individuals who abuse CNS stimulants may chew, snort, inject, or use other unapproved routes of administration, which can result in overdose and death [see OVERDOSAGE (10)].~~ ~~To reduce the abuse of [DRUG-X], assess the risk of abuse prior to prescribing. After prescribing, keep careful prescription records, educate patients and their families about abuse and on proper storage and disposal of CNS stimulants, monitor for signs of abuse while on therapy, and re-evaluate the need for [DRUG-X] use.~~	continuing drug use despite harmful consequences, giving a higher priority to drug use than other activities and obligations), and possible tolerance or physical dependence. **Misuse and abuse of [insert active ingredient] may cause increased** heart rate, respiratory rate, or blood pressure; sweating; dilated pupils; hyperactivity; restlessness; insomnia; decreased appetite; loss of coordination; tremors; flushed skin; vomiting; and/or abdominal pain. Anxiety, psychosis, hostility, aggression, and suicidal or homicidal ideation have also **been observed with CNS stimulants abuse and/or misuse. Misuse and abuse of CNS stimulants, including DRUG-X, can result in overdose and death [see Overdosage (10)], and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.**
Physical Dependence [DRUG-X] may produce physical dependence ~~from continued therapy~~. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug. Withdrawal symptoms after abrupt cessation ~~following prolonged high-dosage administration of~~ CNS stimulants include dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation. **Tolerance** [DRUG-X] may produce tolerance ~~from continued therapy~~. Tolerance is a physiological state characterized by a reduced response to a drug after repeated administration (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose).	**Physical Dependence** DRUG-X may produce physical dependence. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug. Withdrawal **signs and symptoms after abrupt discontinuation or dose reduction following prolonged use of CNS stimulants including DRUG-X include** dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation. **Tolerance** DRUG-X may produce tolerance. Tolerance is a physiological state characterized by a reduced response to a drug after repeated administration (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose).

Table 4. Overdosage

Former*	**New** (reordered information)
~~Manifestations of amphetamine overdose include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states, hyperpyrexia, and rhabdomyolysis. Fatigue and depression usually follow the central nervous system stimulation. Serotonin syndrome has been reported with amphetamine use.~~	**Clinical Effects of Overdose** **Overdose of CNS stimulants is characterized by the following sympathomimetic effects:** **•Cardiovascular effects including tachyarrhythmias, and hypertension or hypotension. Vasospasm, myocardial infarction, or aortic dissection may precipitate sudden cardiac**

~~Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is usually preceded by convulsions and coma.~~ ~~Remove all transdermal systems immediately and cleanse the area(s) to remove any remaining adhesive. The continuing absorption of dextroamphetamine from the skin, even after removal of the transdermal system, should be considered when treating patients with overdose.~~ Dextroamphetamine is not dialyzable. (*moved to Overdose Management*)	**death. Takotsubo cardiomyopathy may develop.** **•CNS effects including psychomotor agitation, confusion, and hallucinations. Serotonin syndrome, seizures, cerebral vascular accidents, and coma may occur.** **•Life-threatening hyperthermia (temperatures greater than 104°F) and rhabdomyolysis may develop.**
Management of Overdose Consult with ~~a Certified~~ Poison ~~Control Center~~ (1-800-222-1222) ~~for up-to-date guidance and advice on the management of overdosage with methylphenidate~~. ~~Provide supportive care, including close medical supervision and monitoring.~~ Treatment should consist of those general measures employed in the management of overdosage with any drug. Consider the possibility of multiple drug ~~overdosages~~. ~~Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. Use supportive and symptomatic measures. Individual patient response to amphetamines varies widely. Toxic symptoms may occur idiosyncratically at low doses~~.	**Overdose Management** Treatment **for CNS stimulant overdose** should consist of those general measures employed in the management of overdose with any drug. Consider the possibility of multiple drug **ingestion. [[for amphetamines state: D-amphetamine is not dialyzable] [for methylphenidate state: Because methylphenidate has a large volume of distribution and is rapidly metabolized, dialysis is not useful]]**. Consider contacting the Poison **Help line** (1-800-222-1222) **or a medical toxicologist for additional overdose management recommendations**.
~~**Disposal**~~ ~~Comply with local laws and regulations on drug disposal of CNS stimulants. Dispose of remaining, unused, or expired [DRUG-X] by a medicine take-back program or at authorized collector registered with the Drug Enforcement Administration. If no take-back program or authorized collector is available, each unused system should be removed from its individual pouch, separated from the protective liner, folded in half, and disposed of in the same manner as used systems.~~	**(Disposal text removed)**

Table 5. Patient Counseling Information

Former*	**New** (added misuse and diversion information)
Advise the patient to read the FDA-approved patient labeling (Medication Guide). ~~**Controlled Substance Status/High Potential for Abuse and Dependence**~~ ~~Advise patients that [DRUG-X] are controlled substances, and they can be abused and lead to dependence.~~ Instruct patients that they should not give [DRUG-X] to anyone else. Advise patients to store	Advise the patient to read the FDA-approved patient labeling (Medication Guide). Abuse**, Misuse, and Addiction** Educate patients and their families about the risks of abuse, misuse, and addiction **of DRUG-X, which can lead to overdose and death,** and proper disposal of any unused drug [see Warnings and Precautions (5.1), Drug Abuse and Dependence (9.2)**, and Overdosage**

[DRUG-X] in a safe place, preferably locked~~, to prevent abuse. Advise patients to comply with laws and regulations on drug disposal. Advise patients to dispose of remaining, unused, or expired [DRUG-X] by a medicine take-back program if available [see Boxed Warning, Warnings and Precautions (5.1), Drug Abuse and Dependence (9.1, 9.2, 9.3), How Supplied/Storage and Handling (16)].~~	**(10)**]. Advise patients to store DRUG-X in a safe place, preferably locked, **and instruct patients to not give DRUG-X to anyone else**.

NOTE: FDA defines *misuse* as the intentional use, for therapeutic purposes, of a drug in a manner other than as prescribed or by an individual for whom it was not prescribed. FDA defines *abuse* as the intentional, nontherapeutic use of a drug for its desirable psychological or physiological effects. The term *abuse* is used in this document to describe a specific behavior that confers a risk of adverse health outcomes; it is not intended to imply moral judgment. FDA is committed to reducing stigma, expanding therapeutic options, and ensuring access to evidence-based treatment for individuals with substance use disorders.

Facts about Prescription Stimulants

- Prescription stimulants can help patients: with ADHD stay focused longer, listen better, and fidget less; with a binge-eating disorder, reduce the number of excessive overeating episodes; and with narcolepsy, stay awake during the day.
- Prescription stimulants also carry serious risks, including misuse and abuse, substance abuse disorder and addiction, overdose, and death.
- There are two main categories of prescription stimulants: immediate-release and extended-release. Immediate-release stimulants are usually taken two or three times a day, and extended-release stimulants are taken once a day.
- Prescription stimulants are available in many different formulations, including tablets, capsules, and liquid form.
- Common side effects of prescription stimulants include loss of appetite, trouble sleeping, headache, stomachache, irritability, fast heart rate, and high blood pressure.
- Store your prescription stimulants securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home. Do not share these medicines with anyone else, and immediately dispose of unused or expired prescription stimulants properly or take them to a drug take-back site, location, or program.

Additional Information for Health Care Professionals

- To address continuing concerns of misuse, abuse, and addiction of prescription stimulants, FDA is requiring updates to the *Boxed Warning* and other information to ensure the prescribing information is made consistent across the entire class of these medicines. The current prescribing information in some prescription stimulants does not provide up to date warnings about the harms of misuse and abuse, and particularly that most individuals who misuse prescription stimulants get their drugs from other family members or peers. Further, individuals who are prescribed stimulants are often faced with requests to share their medication. Sharing these medicines with others can lead to development of substance use disorder and addiction in those with whom these drugs are shared.

- Counsel patients not to give any of their medicine to anyone else and monitor for signs and symptoms of diversion such as requesting refills more frequently than needed. As many as half of youth with valid prescriptions for these medicines are approached by peers and other individuals in the person's peer group to sell or give away their medicine.
- Throughout treatment with prescription stimulants, regularly assess and monitor for signs and symptoms of nonmedical use and addiction.
- Keep careful records of prescribing information, including quantity, frequency, and renewal requests, as required by state and federal laws.
- Educate patients and caregivers on the importance of proper storage and disposal of prescription stimulants.
- Advise patients and caregivers that taking a prescription stimulant other than how it is prescribed, or together with alcohol or other controlled substances, could increase the risk of overdose and death.
- Inform patients and caregivers how to recognize the signs and symptoms of an overdose.
- Counsel patients that nonmedical use of prescription stimulants can cause anxiety, nervousness, loss of appetite, and sleep deprivation—all of which can interfere with studying and performance on exams.
- Encourage patients to read the Medication Guide they receive with their filled prescription(s). This important information will be included, as well as additional information about the medicine.
- To help FDA track safety issues with medicines, report adverse events involving prescription stimulants or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

Additional Information for Patients, Caregivers, and Others

- To address continuing concerns of misuse, abuse, and addiction of prescription stimulants, FDA is requiring updates to the *Boxed Warning* and other information to ensure the prescribing information is made consistent across the entire class of these medicines.
- The current prescribing information in some prescription stimulants does not provide up to date warnings about the harms of misuse and abuse, and particularly that most individuals who misuse prescription stimulants get their drugs from other family members or peers. Individuals prescribed stimulants also are often faced with requests to share their medication. Sharing these medicines can lead to the development of substance use disorder and addiction in those with whom these drugs are shared.
- Even when prescription stimulants are taken as prescribed by a health care professional, they can lead to misuse and abuse, also called nonmedical use, and addiction, which can lead to overdose and death.
- The risk of overdose and death is increased with higher doses or when a pill is manipulated (e.g., crushed or made into a liquid form) and snorted or injected.
- Take prescription stimulants exactly as your health care professional prescribes.
- Do not take larger doses than prescribed.
- Do not take them more frequently than prescribed.

- Using prescription stimulants, which are controlled substances, without a doctor's prescription or misusing someone else's prescription is dangerous and is against the law.
- Do not purchase prescription stimulants from dealers or illegal online sellers. Taking prescription stimulants not prescribed to you may be harmful, and illegal sellers may provide falsified products that appear to be legitimate prescription products but contain dangerous illicit drugs like fentanyl or methamphetamine, which can have fatal consequences.
- Do not take prescription stimulants with alcohol or other controlled substances like opioids, if they are not prescribed for you, as this can have serious and possible deadly consequences.
- Seek medical attention immediately by going to an emergency room or calling 911 if you experience serious side effects or symptoms of stimulant overdose, which can lead to a heart attack, stroke, or seizures. Symptoms may include:
    - Fast heart rate
    - Fast breathing
    - Increased blood pressure
    - Dilated pupils
    - Restlessness
    - Tremors
    - Overactive reflexes
    - Loss of coordination
    - Muscle pain
    - Stomach cramps
    - Nausea and vomiting
    - Aggressive behavior
    - Panic
    - Confusion
    - Hallucinations
- Talk to your health care professional if you have questions or concerns about the risks of taking prescription stimulants.
- Many who take unprescribed prescription stimulants experience anxiety, nervousness, loss of appetite, and sleep deprivation—all of which can interfere with studying and performance on exams.
- Store your prescription stimulants securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home. Do not share these medicines with anyone else, and immediately dispose of unused or expired prescription stimulants properly or take them to a drug take-back site, location, or program.
- Read the patient Medication Guide that comes with your filled prescription(s). This important information will be included, and there may be additional information about your medicine. The Medication Guide explains the important things you need to know about the medicine. These include the side effects, what the medicine is used for, how to take and store it properly, and other things to watch out for when you are taking the medicine.
- To help FDA track safety issues with medicines, report side effects from prescription stimulants or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.
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Background Summary

We reviewed the medical literature published from January 2006 to May 2020 on adverse events associated with misuse and abuse, also known as nonmedical use, of prescription stimulants. Our review found the most common source of prescription stimulants for nonmedical use was from family members and friends, and those in an individual's peer group. These shared medications are usually provided for free[1,2] and are not from users' own prescriptions, with estimates generally ranging from 56 percent to 80 percent.[3-8] In general, people use these medicines nonmedically thinking they will enhance work or academic performance,[1,2,7,9] and less commonly for recreational or social reasons.[1,2,7,9]

Our review found that nonmedical use has remained relatively stable over the past two decades[9,10] despite the increasing number of prescription stimulants dispensed. Overall, the dispensing for Schedule II stimulants increased over the last three decades, almost doubling in the past 10 years from approximately 12.5 million prescriptions in the first quarter of 2011 to 20 million in the first quarter of 2022.[11] The prevalence of nonmedical use of prescription stimulants varies across specific subpopulations and is highest in young adults (past-year prevalence estimates ranged from 4.1 percent to 7.5 percent),[12,13] people in college (nationally representative estimate of past-year prevalence 4.3 percent),[14] and people diagnosed with ADHD (past-year prevalence ranged from 14 percent to 32 percent).[15-18] Nonmedical use of prescription stimulants is most common in young adults ages 18 to 25,[12,13] and often begins in early adulthood.[19-22] In general, people who use prescription stimulants nonmedically do so infrequently, with approximately 50 percent to 75 percent reporting nonmedical use less than or equal to once a month,[19,23] although some college students reported doing so more frequently.[19,23]

People who use prescription stimulants nonmedically may have a higher risk of developing a substance use disorder[24,25,26] than those who do not. Use of other substances in the past year is common among those who use prescription stimulants nonmedically.[7,23,27,28] Common substances include alcohol, marijuana, cocaine, and opioids.[7,23,27,28] Data suggest that college students who nonmedically use prescription stimulants may not perceive polysubstance use as a risky behavior.[29]

Among those presenting with an acute adverse event related to their nonmedical use of prescription stimulants, the most severe harms are more commonly observed when the nonmedical use was by a non-oral route, as observed in data from U.S. poison centers. Among poison center cases with documentation of nonmedical use of a schedule-II prescription stimulant[30] from 2001 to 2018, approximately 70 percent of cases that mentioned an injection route had a related medical outcome with clinical effects that were moderate (i.e., prolonged or systemic in nature and usually requiring treatment)[31] or major (i.e., life-threatening or resulting in significant residual disability).[32] Approximately 65 percent of nasal/inhalation and approximately 56 percent of oral route cases had a related medical outcome with a moderate or major effect.

Deaths involving stimulants continue to increase and often involve multiple substances, such as opioids.[33] Deaths involving illicit stimulants or opioids outnumber deaths involving prescription stimulants.[34] People seeking to illegally obtain prescription stimulants from others have been exposed to greater risks in recent years because of the increasing presence of illicit sellers offering falsified prescription stimulant products that contain harmful substances such as methamphetamine or fentanyl.[35-38]

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30. In America's Poison Centers database, National Poison Data System, route is provided at the level of the case rather than for each involved substance. Therefore, in the assessment of routes of prescription stimulant nonmedical use, the cases were limited to those that only mentioned involvement of a prescription stimulant. Cases were further limited to those with medical outcomes that were considered related to the exposure.
31. America's Poison Centers definition of Moderate Effect: The patient exhibited symptoms as a result of the exposure which are more pronounced, more prolonged or more of a systemic nature than minor symptoms. Usually, some form of treatment is or would have been indicated. Symptoms were not life-threatening, and the patient has returned to a pre-exposure state of well-being with no residual disability or disfigurement.

32. America's Poison Centers definition of Major Effect: The patient has exhibited symptoms as a result of the exposure which were life-threatening or resulted in significant residual disability or disfigurement.
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Related Information

- Controlled Substances Program: Future public conference planning to discuss topics related to ADHD stimulants
- Information about Medications Used to Treat Attention-Deficit/Hyperactivity Disorder (ADHD)
- Prescription Stimulants DrugFacts
- 5 Myths About Stimulant Abuse
- Prescription Stimulant Misuse and Prevention Among Youth and Young Adults
- Drug Diversion
- Disposal of Unused Medicines: What You Should Know
- Lock it Up: Medicine Safety in Your Home
- The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective
- Think It Through: Managing the Benefits and Risks of Medicines