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INSIGHT

Xylazine: Considerations for Federal Control

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Xylazine is a sedative drug used in veterinary medicine. It is not approved or intended for human consumption. Some drug users intentionally consume xylazine in combination with drugs of abuse, such as illicit fentanyl, to strengthen its effects, while other users are unaware that xylazine is sometimes added to illicit opioids as an adulterant. Xylazine is also used in drug-facilitated crimes to induce a state of unconsciousness. The Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), and Office of National Drug Control Policy have issued warnings regarding the risks of humans consuming xylazine, and media reports indicate the substance is worsening addiction and causing physical wounds among those who use illicit opioids.

Xylazine is not currently controlled under the Controlled Substances Act (CSA). As Congress weighs the legitimate use of xylazine and the risk it poses to public safety and health, it might consider making it a controlled substance under the CSA, thereby allowing DEA to regulate the substance.

The Legitimate Use and Adverse Effects of Xylazine

Veterinarians use xylazine on cattle, horses, and cervidae (e.g., deer) animals as a sedative and pain reliever. According to FDA, "it is not safe for use in humans and may result in serious and life-threatening side effects that appear to be similar to those commonly associated with opioid use, making it difficult to distinguish opioid overdoses from xylazine exposure." Xylazine can increase the risk of fatal overdose because it can cause respiratory depression, low blood pressure, and slowed heart rate.

Xylazine is not an opioid, and therefore opioid overdose reversal drugs, such as naloxone, do not counteract its effects. According to the CDC naloxone may be less effective in reversing an opioid-related overdose if illicit opioid substances contain xylazine because xylazine can heighten the sedation and respiratory effects of opioids. Several states have reported increases in xylazine-involved overdose deaths, although the prevalence of xylazine in drug overdose deaths has not been extensively studied. Xylazine consumption in humans can reportedly cause "wounds that erupt with a scaly dead tissue" that left untreated can lead to the need for amputation.

FDA has restricted the import of unapproved xylazine and has collaborated with U.S. Customs and Border Protection to limit the illicit spread of xylazine while maintaining availability for its legitimate use. DEA reports increasing xylazine encounters across the United States, most commonly in the Northeast. Xylazine is frequently found in polydrug mixtures, often in mixtures containing illicit fentanyl.

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Current Status of Xylazine and Considerations in Scheduling

Xylazine is not a controlled substance under the CSA; however, it is subject to regulation under the Federal Food, Drug, and Cosmetic Act and some state laws. Because xylazine is not scheduled under the CSA, DEA currently does not have the authority to control it. Either Congress or DEA (in conjunction with FDA) could decide to schedule xylazine. The CSA-required process for DEA and FDA to schedule a substance can be time consuming, whereas Congress may pass (and the President may sign) a bill scheduling a substance and is not bound by the CSA's procedural requirements.

Scheduling under the CSA

The CSA established five schedules in which substances may be classified. Schedule I is the most restrictive, containing substances with no accepted medical use and a high potential for abuse. Scheduling controlled substances normally occurs through designated procedures.

Permanent Scheduling Procedures

The Attorney General (AG), through DEA, and in consultation with the Department of Health and Human Services/FDA, may place substances into schedules under the CSA based upon eight factors: (1) actual or relative potential for abuse; (2) known scientific evidence of pharmacological effects; (3) current scientific knowledge of the substance; (4) history and current pattern of abuse; (5) scope, duration, and significance of abuse; (6) risk to public health; (7) psychic or physiological dependence liability; and (8) whether the substance is an immediate precursor of an already-scheduled substance. Congress may also add a substance to a schedule through legislation.

Temporary/Emergency Scheduling Procedures

In 1984, Congress gave the AG the authority to temporarily place a substance into Schedule I of the CSA to "avoid imminent hazards to public safety." To do so, the AG (through DEA) must consider the drug's history and current pattern of abuse; scope, duration, and significance of abuse; and risk to public health. Emergency scheduling may be used to place substances into Schedule I only. It may last for up to two years, with a one-year extension available in some circumstances.

The regulatory controls that apply to a substance depend on the schedule in which it is classified. Congress or DEA could schedule xylazine in Schedules I-V or decide not to schedule xylazine at all. Given that xylazine has accepted use in veterinary medicine, it is unlikely DEA would take steps to emergency schedule it in Schedule I. Placement in Schedule II would affect the availability and handling of xylazine, but, unlike a Schedule I placement, it would still be available for accepted medical use. As a Schedule II controlled substance, it would be subject to annual quota limitations, stricter storage requirements than uncontrolled substances or those on Schedules III-V, and other more stringent DEA regulations.

Scheduling a substance has implications for those who violate the CSA, as well as for the federal criminal justice system as a whole. Penalties for illicit manufacturing, possession, and trafficking of controlled substances range from fines to life in prison and some CSA crimes are punishable by death, depending on a number of factors pursuant to the crime. Factors considered in federal sentencing include, but are not limited to, the number of offenders, the schedule and quantity of the drug, the number of prior offenses, and aggravating factors (e.g., causing death, weapons involved). As of July 22, 2023, of the 158,263 federal inmates for whom offense data are known, 65,536 (41.5%) are serving sentences for federal drug offenses. It is unknown whether or how the relative number of drug offenders might change if xylazine were to be scheduled.

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