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Legal Sidebar

Xylazine and the Controlled Substances Act: Legal Considerations for Congress

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Xylazine, sometimes colloquially called "tranq," is a sedative and analgesic that has been approved by the Food and Drug Administration (FDA) for use in animals. Xylazine is not approved or intended for human use but is sometimes used by humans, either alone or in combination with other drugs of abuse such as illicit fentanyl. Human use of xylazine can pose serious health risks. FDA and the Drug Enforcement Administration (DEA) have issued warnings about xylazine, and the Office of National Drug Control Policy officially designated fentanyl adulterated with xylazine as an emerging threat to the United States.

In light of the health risks associated with xylazine, some have called for it to be controlled under the federal Controlled Substances Act (CSA). Others oppose CSA control. A CRS Insight discusses policy considerations related to federal regulation of xylazine. This Legal Sidebar outlines the current federal legal regime that applies to xylazine. It then discusses possible CSA control of the substance and related considerations for Congress.

Xylazine and Federal Drug Law

Pharmaceutical drugs such as xylazine may be subject to multiple overlapping regulatory regimes under federal and state law. At the federal level, all pharmaceutical drugs sold in the United States are subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act), which, among other things, seeks to protect consumers from obtaining unsafe or ineffective drugs and other products through commercial channels. The FD&C Act prohibits the "introduction or delivery for introduction into interstate commerce" of any drug "that is adulterated or misbranded." FDA is primarily responsible for enforcing the FD&C Act.

Some pharmaceutical drugs, including veterinary medications, are also classified as controlled substances under the CSA. The CSA aims to protect public health from the dangers of addictive or dangerous drugs and other substances while also ensuring that patients have access to controlled pharmaceutical drugs for legitimate medical purposes. To advance those goals, the CSA requires entities engaged in legitimate activities involving controlled substances to register with DEA and take steps to prevent diversion and misuse. The act also imposes criminal penalties for various unauthorized activities involving controlled substances. DEA is primarily responsible for enforcing the CSA.

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Drugs generally become subject to the CSA by being placed in one of five lists, known as Schedules I-V. Either Congress or DEA (in conjunction with the Department of Health and Human Services) can schedule a controlled substance. A lower schedule number corresponds to greater restrictions, so substances in Schedule I are subject to the strictest controls, while substances in Schedule V are subject to the least strict controls. Among pharmaceutical drugs, the CSA primarily applies to prescription drugs, not drugs available over the counter. The statute does not apply to all prescription drugs. Instead, it applies to the subset of pharmaceutical drugs deemed to pose a significant risk of abuse and dependence. (In addition to pharmaceutical drugs, the CSA imposes controls on some recreational drugs and other substances that are not regulated under the FD&C Act.)

Currently, xylazine is regulated under the FD&C Act but not the CSA. Like other drugs, xylazine is also subject to regulation under state law. Several states have taken steps to regulate xylazine under state controlled substances laws.

Proposed CSA Regulation of Xylazine

Several proposals from the 118th Congress would regulate xylazine under the CSA. A provision of the Support for Patients and Communities Reauthorization Act (H.R. 4531), which passed the House in December 2023, would place xylazine in Schedule III, except to the extent the substance is an FDA-approved animal drug whose "use or intended use conforms to the approved application, including the manufacturing, importation, holding, or distribution for such use." The bill would provide for tracking of xylazine in the Automation of Reports and Consolidated Orders System (ARCOS), a nationwide system for reporting transactions involving controlled substances, and require DEA and FDA to prepare certain reports to Congress related to xylazine.

The Combating Illicit Xylazine Act (H.R. 1839, S. 993) would amend the CSA to ban certain activities involving "xylazine for illicit uses." The bill would define *illicit uses of xylazine* to include "[a]ny use in the human species" and "[a]ny use that is not a licit use." It would further define *licit use of xylazine* to include the manufacturing, importation, or use of xylazine in FDA-approved drugs or the administration of such drugs to animals. The proposal would not add xylazine to the schedules of controlled substances, but it would impose penalties for illicit activities involving xylazine equivalent to penalties for unauthorized activities involving Schedule III controlled substances. It would also provide for ARCOS tracking of xylazine and require DEA and FDA to prepare reports to Congress related to xylazine.

In contrast to the two foregoing proposals, both of which would increase controls on xylazine, the Fentanyl Safe Testing and Overdose Prevention Act (S. 2569) would amend the CSA to clarify that the possession, sale, purchase, importation, exportation, or transportation of equipment that tests drugs for the presence of fentanyl or xylazine is not included in the CSA's prohibitions on drug paraphernalia.

Considerations for Congress

A key consideration related to possible CSA control of xylazine is how to maintain access to the drug for legitimate veterinary purposes while preventing unauthorized human use. Xylazine is currently used legitimately on pets, wildlife, zoo animals, and livestock. If xylazine were scheduled under the CSA, any person handling the substance would need to register with DEA and comply with the CSA's regulatory requirements unless the person qualified as an "ultimate user" who possessed the substance for use on "an animal owned by him or by a member of his household." Some stakeholders who currently use xylazine on animals without DEA registration have raised concerns about the possible regulatory burden associated with CSA scheduling.

DEA has the authority impose CSA controls on xylazine through administrative rulemaking. Since the enactment of the CSA, most scheduling actions have been taken via DEA rulemaking, though at times

Congress has scheduled substances via legislation. The CSA rulemaking process delegates scheduling decisions to agencies with relevant expertise, with an opportunity for input by members of the public, but the Act provides DEA with limited options for scheduling controlled substances and regulating them once scheduled. The CSA established Schedules I-V, with each schedule carrying a defined set of regulatory controls and penalties for unauthorized activities. If DEA decided to control xylazine under the CSA, it would need to place the substance in one of the existing schedules. The agency has asserted some authority to tailor controls to specific substances, but it cannot create new schedules or implement regulations or exceptions from control that are not authorized under the CSA. Recent decisions of the Supreme Court may further limit agency discretion to administer federal statutory regimes such as the CSA.

If Congress determined that xylazine should be controlled under the CSA but none of the existing schedules was appropriate, it could enact legislation imposing specified controls without scheduling the substance, as proposed in the Combating Illicit Xylazine Act. It could also schedule xylazine subject to certain exceptions, as proposed in the Support for Patients and Communities Reauthorization Act. Congress has broad legal authority to amend the CSA and has previously enacted legislation imposing targeted regulations on specific substances. For instance, the CSA imposes additional registration requirements on DEA-registered opioid treatment programs and sets mandatory minimum prison sentences for offenses involving threshold quantities of certain specific controlled substances. Tailored regulation such as these measures or the xylazine-related proposals discussed above would likely need to be imposed via legislation rather than DEA rulemaking.

Congress could also consider ways to regulate xylazine other than amending the CSA. The 118th Congress has enacted one such piece of legislation. The TRANQ Research Act of 2023 (P.L. 118-23), enacted in December 2023, requires the National Institute of Standards and Technology to coordinate science and research activities regarding illicit drugs containing xylazine, novel synthetic opioids, and other substances of concern. It also requires the Government Accountability Office to conduct a study on the capabilities of the federal government to detect, identify, and otherwise respond to threats posed by new psychoactive substances, such as xylazine.

Some Members of 118th Congress have introduced other proposals related to xylazine outside the context of the CSA. Multiple proposals—including the Test Strip Access Act of 2023 (H.R. 4106), the Preventing Overdoses with Test Strips Act (H.R. 5801), the Advancing Lifesaving Efforts with Rapid Test strips for Communities Act (ALERT Communities Act; H.R. 7226, S. 2919), and a section of the Support for Patients and Communities Reauthorization Act, discussed above—would authorize the use of grant funds for fentanyl and xylazine test strips and, in some cases, require research with respect to test strips. The Expanding Nationwide Access to Test Strips Act (S. 2484) would ban states from prohibiting individuals from obtaining, possessing, distributing, or using fentanyl or xylazine test strips. The STOP TRANQ Act (S. 4025) would include the identification of countries that are significant sources of xylazine in the annual International Narcotics Control Strategy Report.

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