Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000

Governor Sarah Huckabee Sanders

Renee Mallory, RN, BSN, Secretary of Health

Jennifer Dillaha, MD, Director

PUBLIC COMMENT REPORT

Proposed Rules Pertaining to the List of Controlled Substances in Arkansas

PUBLIC COMMENTS:

Public comment period expired January 29, 2024. A public hearing was held at the Department of Health, 4815 W. Markham St., Little Rock, Arkansas on January 22, 2024. A notice of the public comment period and the public hearing was posted in newspaper on December 22, 2023, December 23, 2023, and December 24, 2023. In addition, a second notice was also posted in the newspaper on December 30, 2023, December 31, 2023, and January 1, 2024, extending the public comment period to January 29, 2024.

The Department received approximately fourteen comments, written and verbal, during the public comment period. All of the noted comments received indicated concerns and conveyed information regarding the scheduling of xylazine, specifically concerns recommending an exemption for veterinary use. (Comments received are attached.)

AGENCY RESPONSE:

Upon review and consideration of the concerns raised by members of the public and industry professionals the Department is withdrawing its proposed scheduling of xylazine and will proceed with the remaining proposed amendments to the List of Controlled Substances.

The Department will further review the potential scheduling of xylazine, to include any input or recommendations from the Drug Enforcement Administration or other experts, as well as potential exemption for legitimate veterinary use before the next proposed amendments to the List are presented.

Shane David

From: Shane David
Sent: Wednesday, January 10, 2024 1:15 PM
To: Kate Williams
Cc: Laura Shue (ADH); S.Craig Smith; Charles Thompson (ADH)
Subject: RE: Xylazine

Good afternoon Dr. Williams,

I have received your public comment. It will be included in our public comment report that will be available on our website after conclusion of the public comment period, along with the Department's response.

Thanks,

Shane

From: Kate Williams <katewilliamsdvm@gmail.com>
Sent: Tuesday, January 9, 2024 5:19 PM
To: Shane David <Shane.david@arkansas.gov>
Subject: Re: Xylazine

You don't often get email from katewilliamsdvm@gmail.com. Learn why this is important

Shane,

Please see attached background information pertaining to xylazine.

I recommend that the Arkansas Dept of Health Pharmacy shadow the language in the Support Act to keep xylazine in the hands of veterinarians as federal law allows and to not schedule on the state level this very important veterinary use drug as a CS Schedule III.
Veterinarians are not the source of the illegal use of xylazine, illegal raw ingredients (powdered raw xylazine) in the hands of drug cartels when mixed with fentanyl, etc are the source of the illegal drug. Why make it more difficult for veterinarians to procure, store or use a "veterinary use only" FDA approved drug within their daily practices. Additionally, since xylazine is a veterinary use drug, the CS scheduling could entice legitimate manufacture of xylazine for sale to veterinarians to stop due to overwhelming government oversight. There is no other drug to replace xylazine in the veterinary market. Since surrounding states (OK) have currently exempt xylazine from scheduling for veterinarians, (I think LA and TN are working on legislation as well), I recommend the state of AR mirror the Support Act language to keep xylazine off the CS list and within the hands of the veterinarians.
Once again, I appreciate your attention in this matter and I am available as needed to answer questions regarding the Xylazine scheduling and concerns within the veterinary community.

Kate Williams, DVM
(479) 633-1317

On Tue, Jan 9, 2024 at 1:10 PM Kate Williams <katewilliamsdvm@gmail.com> wrote:

Shane,

I am reaching out to you regarding the Arkansas Department of Health, Pharmacy Services issuance of a meeting notice on 1/23/2024 regarding xylazine. Xylazine is a very important drug for use in veterinary medicine used for sedation, anesthesia and analgesia in animals such as horses, cattle and other animals. Can you assist me with understanding of the Ar Department of Health's proposed plan to schedule Xylazine as CS III in the state of Arkansas? I am a member of the Arkansas Veterinary Medical Association and serve on the American Veterinary Medical Association, House of Delegates representing Arkansas. After participating in proposed legislation of xylazine on the federal level, I would like to understand the proposal for the upcoming meeting since any action/recommendation will impact the veterinarians in the state of Arkansas.
Please feel free to call me at (479) 633-1317 or via email, katewilliamsdvm@gmail.com. I appreciate your time and look forward to hearing from you.

Kate Williams, DVM, MS

Medical Director/Veterinarian
St Francis Animal Hospital
121 Virginia St
Springdale, AR 72764
cell: 479-633-1317
katewilliamsdvm@gmail.com
sfahdvm@gmail.com

Xylazine: an essential animal sedative used across veterinary medicine

Veterinary access to legitimate xylazine must be preserved while combating the emerging public health threat of illicit xylazine

KEY POINTS:

- Xylazine is an essential drug for the safe handling of many species, particularly cattle, given there is no practical alternative for sedation in cattle.
- Any legislative or regulatory interventions to combat illicit xylazine need to safeguard the availability of veterinary prescription xylazine and its responsible use by veterinarians and our clients.
- Scheduling of xylazine without a provision for its unique uses in veterinary medicine will severely disrupt or eliminate the legitimate supply and prohibit critical uses of the drug.
- The AVMA supports public health efforts and policy intended to combat illicit xylazine.

What is the issue?

- Illicit xylazine is being mixed with illicit fentanyl. This potent drug combination poses grave health and safety risks for humans.
- As policy is crafted to help stop the illicit supply, we are concerned that new enforcement tools could severely impact the legal and responsible access and use of xylazine by veterinarians and our clients.
- **Limiting veterinary access to xylazine will jeopardize animal welfare and human safety.**

Why is xylazine so important in veterinary medicine?

- Xylazine is a prescription animal sedative used to facilitate safe medical evaluation, treatment, and surgical care of many species and is critical when working with livestock, zoo, laboratory, and wildlife species.
- In cattle, xylazine is the only safe and effective sedative drug.
- Xylazine can be reversed in veterinary patients, which prevents secondary injuries and allows them to quickly and safely re-enter the herd or the wild.

How is xylazine currently regulated for veterinary use?

- Xylazine is an FDA-approved prescription animal drug that can only be used by or under the order of a licensed veterinarian and can only be dispensed in the course of the veterinarian's professional practice.
- Federal and state laws require all prescription drugs (for people and animals) to be distributed only to those who are legally entitled to obtain and possess them, and veterinarians are required to keep extensive records.
- Manufacturers and distributors have established internal compliance systems to ensure they are only providing products to those legally entitled to them.

Why is the AVMA concerned about scheduling of xylazine without addressing the unique veterinary uses?

- Without legislation from Congress, the AVMA is concerned the DEA will move to schedule xylazine without a veterinary exemption which would limit how veterinarians are able to use the drug.
- Additionally, without federal legislative and regulatory uniformity, some states will individually regulate xylazine creating a patchwork of rules and regulations for manufacturers and distributors to navigate, increasing the likelihood for supply disruption.
- Xylazine is a low-volume, low-margin generic animal drug. If the regulatory burden or facility investments are too high, these manufacturers will likely choose to discontinue production.
- It is our understanding that there is not significant diversion of xylazine from U.S. veterinary supply channels. In discussions with the Administration, federal agencies, and state law enforcement, illicit manufacturing and importation of xylazine from overseas is commonly raised as a concerning source.

Contact: Dr. Lindsey Hornickel at 202-289-3211 or lhornickel@avma.org

Last updated 12/18/23

Xylazine: an essential animal sedative used across veterinary medicine

AVMA
Our Passion. Our Profession.

What type of legislation would the AVMA support?

- The AVMA would support legislation that exempts the legitimate veterinary uses from any policy interventions, such as scheduling. This has been done before for an animal drug and will strike the right balance of protecting communities from illicit xylazine while maintaining critical veterinary access.
- The AVMA supports continued FDA-oversight of xylazine in non-human species as a prescription animal drug.
- The AVMA supports requiring manufacturers and distributors of legitimate xylazine to report sales to the DEA through an existing tracking system (ARCOS) that identifies unusual activity or changes in ordering patterns.

Status of current xylazine legislation:

- Xylazine language was included in H.R. 4531, the Support for Patients and Communities Reauthorization Act, which recently passed the House with overwhelming bipartisan support on a vote of 386-37. The included provision schedules xylazine as a Schedule III drug and exempts the FDA-approved veterinary product and its use from scheduling. The Senate will now consider the House version of the bill.
- Additionally, H.R. 1839/S. 993 Combating Illicit Xylazine Act is a bipartisan, bicameral bill that would help combat illicit xylazine trafficking while maintaining veterinarians' access under its current prescription status.

Contact: Dr. Lindsey Hornickel at 202-289-3211 or lhornickel@avma.org

Last updated 12/18/23

FOR MORE INFORMATION
Colin MacCarthy
Phone: 202-641-2533**Cell:** 202-641-2533
FOR IMMEDIATE RELEASE: 07/19/2023

(WASHINGTON, DC) July 19, 2023 — The House Energy and Commerce Committee passed the SUPPORT Act - a legislative package aimed to address the growing threat of the opioid crisis, which includes key components of the AVMA-endorsed Combating Illicit Xylazine Act. After sustained advocacy efforts from the AVMA, **the language within the SUPPORT Act would schedule xylazine as a Schedule III drug while exempting from scheduling the FDA-approved animal drug, which means that veterinarians will be able to use it as they always have under federal law.**

Illicit xylazine has now been found across the country mixed with fentanyl and other narcotics. This potent drug combination poses grave health and safety risks to human users. In veterinary medicine, xylazine is an important prescription sedative used to facilitate the safe handling and treatment of many species and is particularly important for use in cattle, horses, wildlife, and research species.

In both the House and Senate, the AVMA helped develop, introduce, and build support for the bipartisan Combating Illicit Xylazine Act. In this bill, anyone involved with the manufacturing, distribution, dispensing, or possession of xylazine with the intent to traffic for human use would be subject to Schedule III penalties under the federal Controlled Substances Act. At the same time, the legitimate veterinary uses would remain under their current prescription status.

The AVMA remains supportive of the approach taken in both the SUPPORT Act and the Combating Illicit Xylazine Act as they both equip the DEA with resources to address illicit xylazine while maintaining veterinary access to the animal drug at its current prescription status under the Food and Drug Administration (FDA).

"The House Energy and Commerce Committee advancing key components of the Combating Illicit Xylazine Act represents months of collaborative work between the AVMA, congressional offices, federal agencies, and other stakeholders," said Dr. Rena Carlson, AVMA President. "The AVMA appreciates the dedication lawmakers have demonstrated to address the public health crisis of illicit xylazine while at the same time understanding how essential the animal sedative is to veterinary medicine. On behalf of the veterinary community, we are incredibly appreciative of the strong leadership demonstrated by Reps. August Pfluger, Jimmy Panetta, Gus Bilirakis, and Ken Buck, and Senators Catherine Cortez Masto, and Chuck Grassley - the steadfast congressional champions of this legislation that protects public health and animal welfare. Thank you to Chairwoman Cathy McMorris Rodgers and Ranking Member Frank Pallone for their bipartisan support in recognizing the need to advance this legislation as part of the Committee's public health initiatives. This policy strikes a well-balanced approach and the AVMA will continue its efforts in both chambers to ensure this policy is signed into law."

Reps. Pfluger, Panetta, Bilirakis, and Buck issued the following statements:

"The drug crisis in our country is becoming more tragic by the day, with drug traffickers turning to an important veterinary tranquilizer to make drugs more addictive—and more deadly," said Rep. Plufger. "I am proud that the SUPPORT Act builds upon my legislation with Rep. Panetta to address illicit xylazine use while protecting access to the critical drug for veterinary use."

"The rise of xylazine-adulterated fentanyl threatens public health and public safety in communities throughout our country," said Rep. Panetta. "After seeing the threat start to grow, I authored the bipartisan Combating Illicit Xylazine Act to take a proactive and targeted approach to regulating xylazine's use in veterinary medicine while ensuring that our law enforcement has the tools they need to prevent its abuse. We just took another important step forward in this fight, and I'll continue to work alongside my partners both in and out of Congress to deliver the urgent action needed to confront this crisis head-on."

"Our goal is to save lives and to make sure law enforcement has the tools it needs to respond appropriately to those who are making these deadly concoctions that are killing so many of our neighbors," said Rep. Bilirakis. "At the same time, we must ensure that those veterinarians who are using xylazine for legitimate purposes have the ability to continue doing so. Our legislation strikes that right balance."

"The opioid epidemic has taken far too many lives across our country, including in my own home state of Colorado. Adding the deadly fentanyl adulterant xylazine to the Controlled Substances Act would save lives and prevent needless opioid overdoses," said Rep. Buck. "The Combating Illicit Xylazine Act would give law enforcement the tools necessary to stop this drug from wreaking havoc in our most vulnerable communities while also protecting the rights of veterinarians and cattlemen to use xylazine legally."

About the AVMA

Serving more than 100,000 member veterinarians, the AVMA is the nation's leading representative of the veterinary profession, dedicated to improving the health and wellbeing of animals, humans and the environment. Founded in 1863 and with members in every U.S. state and territory and more than 60 countries, the AVMA is one of the largest veterinary medical organizations in the world. Informed by our members' unique scientific training and clinical knowledge, the AVMA supports the crucial work of veterinarians and advocates for policies that advance the practice of veterinary medicine and improve animal and human health.

Shane David

From: Shane David
Sent: Wednesday, January 10, 2024 5:05 PM
To: Everett Rogers
Cc: S.Craig Smith; Charles Thompson (ADH); Laura Shue (ADH)
Subject: RE: Xylazine Pharmacy Board Regulation

Good afternoon Dr. Rogers,

I have received your public comment. It will be included in our public comment report that will be available on our website after conclusion of the public comment period, along with the Department's response.

Thanks,

Shane

From: Everett Rogers <everettrogers@hotmail.com>
Sent: Wednesday, January 10, 2024 4:30 PM
To: Shane David <shane.david@arkansas.gov>
Cc: Arkansas VMA <arkansasvma@comcast.net>; Everett Rogers <everettrogers@hotmail.com>
Subject: Xylazine Pharmacy Board Regulation

Mr. David,

Attached please find a PDF letter for public comment regarding proposed changes in the Controlled Substance List for Xylazine hearing on January 23, 2024.

Sincerely,
Everett Rogers, DVM, President
Arkansas Veterinary Medical Association
1404 Clover Circle
Paragould, AR 72450-4868
(870) 236-0778
everetetrogers@hotmail.com

January 10, 2024

Arkansas Department of Health
Center for Health Protection, Pharmacy Services Section

Ref: Proposed changes in the Controlled Substance List Summary (Final) 002:
"10. Xylazine. Xylazine is utilized in veterinarian medicine and would be included into Schedule III. Schedule III,(c), (15)."

The Arkansas Veterinary Medical Association would urge that the commercially available xylazine, for veterinary use, be exempted from being listed as a Schedule III drug when being "dispensed or prescribed for, or administration to, a nonhuman species of a drug containing xylazine that has been approved by the Secretary of Health and Human Services under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. 360b)".

The Veterinary Medical Profession is well aware of and concerned about the illicit use of xylazine. The drug cartels intercept powdered bulk supplies of the product in transit to legitimate production facilities. This powdered product is then mixed with other illicit drugs which are sold on the streets. However, the commercially available xylazine used by veterinary practitioners is a liquid injectable product, which cannot be used to mix with illicit street drugs and is not the source of the illicit use of xylazine. Our profession supports efforts to end the illicit use of all drugs, including xylazine. We would urge and support the criminalization of the illicit use of xylazine punishable as a felony offense.

Xylazine is an essential tool used by veterinary practitioners for the sedation of many species, especially large animals, in order to humanely and safely perform diagnostic and surgical procedures. There are no practical alternatives for sedation in food animals. This drug is a low volume, low margin generic animal drug. If the regulatory burden is too high, the few manufacturers of this product will likely choose to stop production. This would prove disastrous to livestock producers and to food animal veterinary practitioners.
Currently, there are two pieces of federal legislation being considered: HR1839/S993 "Combating Illicit Xylazine Act" and HR4531 "Support for Patients and Communities Reauthorization Act" both of which exempt the FDA approved veterinary product and its use from scheduling and maintain its prescription status. The American Veterinary Medical Association supports both of these pieces of legislation.

Everett Rogers, DVM, President
Arkansas Veterinary Medical Association
1404 Clover Circle
Paragould, AR 72450-4868

Shane David

From: Shane David
Sent: Tuesday, January 16, 2024 10:39 AM
To: Lindy O'Neal
Cc: Laura Shue (ADH); Charles Thompson (ADH); S.Craig Smith
Subject: RE: Veterinary Xylazine Use

Good morning Dr. O'Neal,

I have received your public comment. It will be included in our public comment report that will be available on our website after conclusion of the public comment period, along with the Department's response.

Thanks,

Shane

From: Lindy O'Neal <lindyoneal.dvm@gmail.com>
Sent: Tuesday, January 16, 2024 10:33 AM
To: Shane David <shane.david@arkansas.gov>
Subject: Veterinary Xylazine Use

Hello Mr. David,

My name is Lindy O'Neal, and I am a small animal practitioner in Northwest Arkansas. I own two animal hospitals in Rogers, AR.

I am writing today to offer a perspective regarding the xylazine scheduling and offer support for a veterinary exemption. Right now two neighboring states, Louisiana & Tennessee, have passed a waiver to keep veterinary use of xylazine not-scheduled. The ideal situation would be for Arkansas to also waive xylazine scheduling for veterinary use.

The xylazine problem stems from the powdered form that is coming from Mexico in large quantities (20 pound packages). The veterinary form is a liquid, sold in small quantities of 10, 20 or 50mL bottles. There is no way that the liquid veterinary drug could play a significant part in today's xylazine use problem because it would take SO much of the liquid to convert to powder.

While human medicine does not use this medication, veterinarians count on this mediation on a daily basis. Thankfully, small animal medicine has developed newer medications so I don't personally rely on this medication on a daily basis. But there is NO other approved drug equal to xylazine for use in bovine. If this becomes more highly regulated, the manufacturers within the US may discontinue production of the xylazine due to costs and regulatory burdens. Our cattle industry is struggling enough as it is, please help us by preventing a new barrier for them.

Please let me know if you'd like to talk, I can make myself available. I have attached a document that is more eloquent with wording than I am. Please take time to review it and ask questions if you have any.

Sincerely,

Lindy O'Neal, DVM
1203 S. 43rd Street
Rogers, AR 72758

w. 479.335.1400
c. 501.580.5420
/https://www.amcrogers.com/

Xylazine: an essential animal sedative used across veterinary medicine

AVMA Our Passion. Our Profession.

Veterinary access to legitimate xylazine must be preserved while combating the emerging public health threat of illicit xylazine

KEY POINTS:

- Xylazine is an essential drug for the safe handling of many species, particularly cattle, given there is no practical alternative for sedation in cattle.
- Any legislative or regulatory interventions to combat illicit xylazine need to safeguard the availability of veterinary prescription xylazine and its responsible use by veterinarians and our clients.
- Scheduling of xylazine without a provision for its unique uses in veterinary medicine will severely disrupt or eliminate the legitimate supply and prohibit critical uses of the drug.
- The AVMA supports public health efforts and policy intended to combat illicit xylazine.

What is the issue?

- Illicit xylazine is being mixed with illicit fentanyl. This potent drug combination poses grave health and safety risks for humans.
- As policy is crafted to help stop the illicit supply, we are concerned that new enforcement tools could severely impact the legal and responsible access and use of xylazine by veterinarians and our clients.
- **Limiting veterinary access to xylazine will jeopardize animal welfare and human safety.**

Why is xylazine so important in veterinary medicine?

- Xylazine is a prescription animal sedative used to facilitate safe medical evaluation, treatment, and surgical care of many species and is critical when working with livestock, zoo, laboratory, and wildlife species.
- In cattle, xylazine is the only safe and effective sedative drug.
- Xylazine can be reversed in veterinary patients, which prevents secondary injuries and allows them to quickly and safely re-enter the herd or the wild.

How is xylazine currently regulated for veterinary use?

- Xylazine is an FDA-approved prescription animal drug that can only be used by or under the order of a licensed veterinarian and can only be dispensed in the course of the veterinarian's professional practice.
- Federal and state laws require all prescription drugs (for people and animals) to be distributed only to those who are legally entitled to obtain and possess them, and veterinarians are required to keep extensive records.
- Manufacturers and distributors have established internal compliance systems to ensure they are only providing products to those legally entitled to them.

Why is the AVMA concerned about scheduling of xylazine without addressing the unique veterinary uses?

- Without legislation from Congress, the AVMA is concerned the DEA will move to schedule xylazine without a veterinary exemption which would limit how veterinarians are able to use the drug.
- Additionally, without federal legislative and regulatory uniformity, some states will individually regulate xylazine creating a patchwork of rules and regulations for manufacturers and distributors to navigate, increasing the likelihood for supply disruption.
- Xylazine is a low-volume, low-margin generic animal drug. If the regulatory burden or facility investments are too high, these manufacturers will likely choose to discontinue production.
- It is our understanding that there is not significant diversion of xylazine from U.S. veterinary supply channels. In discussions with the Administration, federal agencies, and state law enforcement, illicit manufacturing and importation of xylazine from overseas is commonly raised as a concerning source.

Contact: Dr. Lindsey Hornickel at 202-289-3211 or lhornickel@avma.org

Last updated 12/18/23

Xylazine: an essential animal sedative used across veterinary medicine

AVMA Our Passion. Our Profession.

What type of legislation would the AVMA support?

- The AVMA would support legislation that exempts the legitimate veterinary uses from any policy interventions, such as scheduling. This has been done before for an animal drug and will strike the right balance of protecting communities from illicit xylazine while maintaining critical veterinary access.
- The AVMA supports continued FDA-oversight of xylazine in non-human species as a prescription animal drug.
- The AVMA supports requiring manufacturers and distributors of legitimate xylazine to report sales to the DEA through an existing tracking system (ARCOS) that identifies unusual activity or changes in ordering patterns.

Status of current xylazine legislation:

- Xylazine language was included in H.R. 4531, the Support for Patients and Communities Reauthorization Act, which recently passed the House with overwhelming bipartisan support on a vote of 386-37. The included provision schedules xylazine as a Schedule III drug and exempts the FDA-approved veterinary product and its use from scheduling. The Senate will now consider the House version of the bill.
- Additionally, H.R. 1839/S. 993 Combating Illicit Xylazine Act is a bipartisan, bicameral bill that would help combat illicit xylazine trafficking while maintaining veterinarians' access under its current prescription status.

Contact: Dr. Lindsey Hornickel at 202-289-3211 or lhornickel@avma.org

Last updated 12/18/23

Shane David

From: Shane David
Sent: Tuesday, January 16, 2024 4:45 PM
To: Rene' LaVergne
Cc: Laura Shue (ADH); S.Craig Smith; Charles Thompson (ADH)
Subject: RE: Xylazine for veterinary use

Good afternoon Dr. LaVergne,

I have received your public comment. It will be included in our public comment report that will be available on our website after conclusion of the public comment period, along with the Department's response.

Thanks,

Shane

From: Rene' LaVergne <cajundvm@gmail.com>
Sent: Tuesday, January 16, 2024 4:24 PM
To: Shane David <shane.david@arkansas.gov>
Subject: Xylazine for veterinary use

> You don't often get email from cajundvm@gmail.com. Learn why this is important

To whom it may concern:
I stand with my veterinary colleagues in asking that Xylazine for prescriptive purposes be preserved and under the direction of a licensed veterinarian with an established doctor, client patient relationship. This drug is the only sedative for safe handling of cattle, and in my small animal hospital, is valuable for the sedation of an injured animal, where general anesthesia is not a viable option.
We are in favor of scheduling the elicit use, diversion of the powder form, mixed with other elicit drugs and sold on the streets. All elicit drug trade poses a threat to our human youth. Our concern is that this valuable drug in the hands of a licensed veterinarian is vital. If the schedule is applied, manufacturers will discontinue production, which will critically affect the safety of cattle producers, veterinarians and the animals themselves.
Please consider following the proposed federal statute that classifies the drug (from elicit channels), while preserving the legitimate veterinary prescriptive use.

Thank you for fighting the good fight,

Rene' LaVergne, DVM
Pinnacle Valley Westrock Animal Hospital
501-878-7375

Shane David

From: Shane David
Sent: Thursday, January 18, 2024 11:55 AM
To: Yahoo Mail
Cc: S.Craig Smith; Charles Thompson (ADH); Laura Shue (ADH)
Subject: RE: Xylazine

Good morning Dr. Helms,

I have received your public comment. It will be included in our public comment report that will be available on our website after conclusion of the public comment period, along with the Department's response.

Thanks,

Shane

From: Yahoo Mail <gatewayanimals@sbcglobal.net>
Sent: Wednesday, January 17, 2024 7:32 PM
To: Shane David <shane.david@arkansas.gov>
Subject: Xylazine

January 17, 2024

Arkansas Department of Health
Center for Health Protection, Pharmacy Services Section

Ref: Proposed changes in the Controlled Substance List concerning Xylazine

Dear Mr. David and whoever else that may be concerned:

I have been a mixed animal practice owner and a predominately large animal veterinarian in the Great State of Arkansas for over 28 years. My practice utilizes Xylazine on a daily basis, whether it be to sedate a small companion animal, a horse, a cow or any other farm animal species. Xylazine is an economical and safe drug for use as a chemical restraint agent.

I believe most veterinary practitioners are fully aware of the abuse of Xylazine within the illicit drug trade. Most of what I read states that the Xylazine creating the abusive drug problem is not coming from veterinary channels; therefore, how is restricting Xylazine in veterinary medicine going to decrease the illicit human abuse of this product? Restricting Xylazine, will in fact, create more work for veterinarians by requiring stricter documentation of when and where it is administered. Without easy access to Xylazine many animals may be made to suffer if an economical alternative can not be secured.

If extra restrictions are placed on Xylazine, it will most likely drive the cost of this product up placing greater financial burdens on both pet and farm animal owners.

Again I ask the question; if the illicit product that is being abused is not believed to be coming from veterinary channels, then how is restricting Xylazine going to decrease the number of human overdoses?

Classifying Xylazine as a controlled substance simply does not make any sense because it will not stop nor will it decrease the human abuse problem.

Sincerely,

Roger Helms, DVM
Gateway Animal Clinic
3219 Hwy 67B North
Walnut Ridge, AR 72466
870-759-1031

870-886-6704
GatewayAnimals@sbcglobal.net

Shane David

From: Shane David
Sent: Thursday, January 18, 2024 12:12 PM
To: Darren McVay
Subject: RE: Xylazine

Good afternoon Dr. McVay,

I have received your public comment. It will be included in our public comment report that will be available on our website after conclusion of the public comment period, along with the Department's response.

Thanks,

Shane

From: Darren McVay <dmcvay865@gmail.com>
Sent: Wednesday, January 17, 2024 9:06 PM
To: Shane David <shane.david@arkansas.gov>
Subject: Xylazine

To whom it may concern,

Veterinarians have long been entrusted as an integral part of ensuring the safety of this nation's (and the world's) food supply. As a practicing food animal veterinarian, I do not take this responsibility lightly. We work hard to continually improve our quality of medicine, and thus positively affect the welfare of all animals entrusted to our care. Veterinarians have non-regulatory, self-imposed bans on medications which we honor and abide by: the voluntary ban on aminoglycosides in food animals. I believe these clearly prove veterinarians have the safety of the public as an utmost priority. The fact that obtaining xylazine for illicit use is outside the veterinary channels indicates no veterinary wrongdoing and should negate any and all efforts to impose needless, burdensome regulations on law abiding veterinarians. Furthermore, increased regulation would likely lead to decreased use by veterinarians, leading to decreased demand, which may very well lead manufacturers to either cease production or increase price incrementally. Ceasing production would remove the ONLY licensed product for chemical restraint of cattle, which is a serious welfare issue. Price increases must be passed on to clients, which places an undue financial burden on the public. These unintended consequences and collateral fallout alone far outweigh any rational attempt to proceed with or even logically consider increased regulation on veterinary xylazine use and would be an egregious leap backward for animal welfare, not forward progress. Any effort in regulating xylazine should specifically exempt veterinary use. The fact that Arkansas is experiencing a shortage of large animal veterinarians is a widely known problem. Xylazine regulation in an individual state will be a repulsion to attracting potential veterinarians interested in practicing in Arkansas, not a draw to our state. This will further compound our large animal shortage. This is yet another negative unintended consequence. When we step back and look at the big picture of illicit xylazine use, the veterinarian is absolutely nowhere in the picture. As a governing body, I

would hope your interest would be to stand with and support the veterinarian, not to oppose the veterinarian and impose burdensome regulations that will have no effect on its intended purpose.

Sincerely,
Darren McVay DVM

Shane David

From: Shane David
Sent: Monday, January 22, 2024 4:21 PM
To: Michelle Bufkin Horton
Cc: Laura Shue (ADH); S.Craig Smith; Charles Thompson (ADH); Connie Melton
Subject: RE: Comment Letter for the Proposed Rule Change - Controlled Substance List

Good afternoon Mr. Bufkin,

I have received your public comment. It will be included in our public comment report that will be available on our website after conclusion of the public comment period, along with the Department's response.

Thanks,

Shane

From: Michelle Bufkin Horton <michelle@arbeef.org>
Sent: Monday, January 22, 2024 3:52 PM
To: Shane David <shane.david@arkansas.gov>
Subject: Comment Letter for the Proposed Rule Change - Controlled Substance List

David,

Attached you will find the comment letter from the Arkansas Cattlemen's Association addressing SUMMARY OF PROPOSED AMENDMENTS TO RULES PERTAINING TO THE LIST OF CONTROLLED SUBSTANCES FOR THE STATE OF ARKANSAS.

Thank you for the opportunity to submit comments. Please let me know if I can provide any more information to you.

Kindly,

Michelle Bufkin Horton
Executive Vice President
Arkansas Cattlemen's Association
Office: 501-224-2114 | Cell: 334-313-2315
www.arbeef.org

Arkansas Cattlemen's Association

www.arbeef.org • 310 Executive Court • Little Rock, Arkansas 72205 • (501) 224-2114

January 22, 2024

Arkansas Department of Health
Center for Health Protection, Pharmacy Services Section

Re: Proposed changes in the Controlled Substance List Summary 002: "10 Xylazine. Xylazine is utilized in veterinarian medicine and would be included into Schedule III.

The Arkansas Cattlemen's Association (ACA) urges the Arkansas Department of Health to exempt the commercially available xylazine, for veterinary use, from being listed as a Schedule III drug when being "dispensed or prescribed for, or administration, to a nonhuman species of a drug containing xylazine that has been approved by the Secretary of Health and Human Services under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A 260b)."

Xylazine is an essential tool for cattle producers to humanely sedate cattle for treatment or to examine the animal. Moving this drug to a Schedule III classification, without exemption, would cause substantial harm to the cattle in our members' care and to the industry. Furthermore, increasing the regulatory burden for manufacturers could create a supply issue, as there are limited manufacturers of xylazine. The end effect would be disastrous to livestock producers and their veterinarians, as there are no practical alternatives for sedation in livestock used for food production.

There are currently two pieces of federal legislation in committee that exempt the FDA-approved veterinary product and its use from scheduling and maintaining its prescription status: HR18369/S993 and HR4531.

While the ACA is aware of the illicit use of xylazine and the dangers it can pose to the public; it is important to note that the commercially available xylazine used by veterinary practitioners and livestock producers is a liquid injectable product, which cannot be used to mix with illicit street drugs.

We appreciate the opportunity to provide these comments and can be reached for any clarification and discussion needed.

Sincerely,

Michelle Bufkin Horton
Executive Vice President
Arkansas Cattlemen's Association

Shane David

From: Shane David
Sent: Tuesday, January 23, 2024 8:29 AM
To: Helen Wick
Cc: S.Craig Smith; Laura Shue (ADH); Charles Thompson (ADH)
Subject: RE: Keeping xylazine exempt from Class III schedule for veterinarians

Good morning Dr. Hoerler,

I have received your public comment. It will be included in our public comment report that will be available on our website after conclusion of the public comment period, along with the Department's response.

Thanks,

Shane

From: Helen Wick <helenwick@gmail.com>
Sent: Monday, January 22, 2024 8:29 PM
To: Shane David <shane.david@arkansas.gov>
Subject: Keeping xylazine exempt from Class III schedule for veterinarians

To the Arkansas Department of Health Center for Health Protection, Pharmacy Services Section ,

Ref: Proposed changes in the Controlled Substance List Summary (Final) 002: "10. Xylazine. Xylazine is utilized in veterinarian medicine and would be included into Schedule III. Schedule III,(c), (15)."

I am a mixed practice veterinarian and regularly use xylazine, especially for large animal sedation. On my food animal farm calls, I often hear from rural farmers and ranchers how difficult it is to even find a veterinarian to come out on a call, much less have it be economical. I can reach for xylazine to sedate a dangerous, injured, or very painful animal, making this much less stressful for both the animal and all the people involved. I always worry about a farmer or farmhand getting injured by an unpredictable animal. With economical and relatively safe sedation provided by xylazine, we can accomplish good veterinary care with fewer people. If this drug becomes controlled, I will have to get my own DEA license, spend extra time with logs, and pay a much higher price for this drug. As a result, I will have to pass on most of this cost to the producer, which fills me with dread knowing that I somehow have to make veterinary care economical for food animals. I don't want to hesitate using a sedative because of its cost or lack of availability, only to put more people in harm's way of a dangerous animal. I don't want to hesitate giving an animal pain relief and preventing further injury.

I am very concerned about keeping our medications out of the wrong hands, and agree that something must be done, but I do not think increasing xylazine to a Schedule III drug will achieve that. I have made it a point to lock up all sedatives to prevent any access, whether accidental or malicious, and I think a lot of other veterinarians are also becoming more cautious. We all need to work together and be creative in finding ways to curb illicit drug use, and many ways do not have to be legislative. In this case, increased regulatory pressure for veterinarians is very unlikely to make a positive difference, and will certainly make a very negative one for the animals under our care.

Sincerely,

Helen Hoerler, DVM
17960 Syble Road
Lincoln, AR 72744
phone 918-575-1514

Shane David

From: Shane David
Sent: Tuesday, January 23, 2024 1:53 PM
To: Sarah Shedenhelm
Cc: S.Craig Smith; Charles Thompson (ADH); Laura Shue (ADH)
Subject: RE: Xylazine

Good afternoon Dr. Shedenhelm,

I have received your public comment. It will be included in our public comment report that will be available on our website after conclusion of the public comment period, along with the Department's response.

Thanks,

Shane

From: Sarah Shedenhelm <sarah.shed@gmail.com>
Sent: Tuesday, January 23, 2024 9:34 AM
To: Shane David <shane.david@arkansas.gov>
Subject: Xylazine

Mr. David,
I'm sure you have received many emails from veterinarians regarding our concern over xylazine becoming a schedule III drug. I will keep this concise. I fully support the request to grant AR veterinarians a waiver to continue to use the veterinary formulation of xylazine without registering as a controlled drug. If this waiver is not granted, the manufactures of our vet formulations will most certainly discontinue manufacturing leaving a devastating impact on cattle medicine. Thank you for considering our request and please reach out if you have any questions.

Sarah Shedenhelm, DVM
870-421-6927

Shane David

From: Shane David
Sent: Tuesday, January 23, 2024 11:30 AM
To: Fuchs, David - FSIS
Cc: S.Craig Smith; Charles Thompson (ADH); Laura Shue (ADH)
Subject: RE: [External Email]Re: Regarding xylazine usage in Veterinary Medicine

Good morning Dr. Fuchs,

I have received your public comment. It will be included in our public comment report that will be available on our website after conclusion of the public comment period, along with the Department's response.

Thanks,

Shane

From: Fuchs, David - FSIS <david.fuchs@usda.gov>
Sent: Tuesday, January 23, 2024 9:31 AM
To: Sarah Shedenhelm <sarah.shed@gmail.com>
Cc: Shane David <shane.david@arkansas.gov>; David Fuchs <david.fuchsdvm@yahoo.com>
Subject: RE: [External Email]Re: Regarding xylazine usage in Veterinary Medicine

You don't often get email from david.fuchs@usda.gov. Learn why this is important

Understood
Thank you very much.

Dr. David C. Fuchs VMO/SPHV
Office of Field Operations Circuit 3502
(P/M112)(P/M112A)(P/M7211)
Food Safety and Inspection Service, USDA
601 Tyson Drive Building 1
Green Forest, AR 72638
Phone: (870) 438-7114
Fax (870)438-5247
Cell (870)577-5543
David.Fuchs@usda.gov

From: Sarah Shedenhelm <sarah.shed@gmail.com>
Sent: Tuesday, January 23, 2024 9:29 AM
To: Fuchs, David - FSIS <david.fuchs@usda.gov>
Cc: shane.david@arkansas.gov; David Fuchs <david.fuchsdvm@yahoo.com>
Subject: [External Email]Re: Regarding xylazine usage in Veterinary Medicine

You don't often get email from sarah.shed@gmail.com. Learn why this is important

[External Email]
If this message comes from an **unexpected sender** or references a **vague/unexpected topic;**

Shane David

From: Fuchs, David - FSIS <david.fuchs@usda.gov>
Sent: Tuesday, January 23, 2024 9:22 AM
To: sarah.shed@gmail.com
Cc: Shane David; David Fuchs
Subject: Regarding xylazine usage in Veterinary Medicine

Dr. Shedenhelm,

If petitions are needed to be signed, I can support this concern.

Thank you for all your works!

Regards

Dr. David C. Fuchs VMO/SPHV
Office of Field Operations Circuit 3502
(P/M112)(P/M112A)(P/M7211)
Food Safety and Inspection Service, USDA
601 Tyson Drive Building 1
Green Forest, AR 72638
Phone: (870) 438-7114
Fax (870)438-5247
Cell (870)577-5543
David.Fuchs@usda.gov

There is no petition that I am aware of. The best thing that you can do is write an email to Shane David expressing your concerns. Tennessee and Louisiana have granted waivers for vet use and so we are simply asking for the same waiver.

Sarah Shedenhelm, DVM

On Tue, Jan 23, 2024 at 9:22 AM Fuchs, David - FSIS <david.fuchs@usda.gov> wrote:

Dr. Shedenhelm,

If petitions are needed to be signed, I can support this concern.

Thank you for all your works!

Regards

Dr. David C. Fuchs VMO/SPHV

Office of Field Operations Circuit 3502

(P/M112)(P/M112A)(P/M7211)

Food Safety and Inspection Service, USDA

601 Tyson Drive Building 1

Green Forest, AR 72638

Phone: (870) 438-7114

Fax (870)438-5247

Cell (870)577-5543

David.Fuchs@usda.gov

Shane David

From: Laura Shue (ADH)
Sent: Thursday, January 25, 2024 7:30 AM
To: lilesanimalclinic@att.net
Subject: Re: Xylazine

Thank you for your comment. It will be included in the public comment report with the agency response.

Laura Shue

From: lilesanimalclinic@att.net <lilesanimalclinic@att.net>
Sent: Thursday, January 25, 2024 2:36 AM
To: Laura Shue (ADH) <Laura.Shue@arkansas.gov>
Subject: Xylazine

[You don't often get email from lilesanimalclinic@att.net. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Ms Shue:
Thank you for working on the xylazine dilemma . It is very important to practitioners in small and especially large animal practice. Encumbering its use could very well cause injury or fatalities among veterinarians , clients, and/or patients.
Does this constitute a written comment, or is it an egregious breach of protocol again ?
Sincerely,
Michael Liles , DVM
501-279-7553.
Sent from my iPhone

Shane David

From: Shane David
Sent: Monday, January 29, 2024 3:53 PM
To: Mark Lambert
Cc: Laura Shue (ADH); Charles Thompson (ADH); S.Craig Smith
Subject: RE: Comments regarding Controlled Substances

Good afternoon Mr. Lambert,

I have received your public comment. It will be included in our public comment report that will be available on our website after conclusion of the public comment period, along with the Department's response.

Thanks,

Shane

From: Mark Lambert <mark.lambert@arfb.com>
Sent: Monday, January 29, 2024 2:20 PM
To: Shane David <shane.david@arkansas.gov>
Subject: Comments regarding Controlled Substances

Mr. David,

Please see the attached comments in regard to Xylazine being listed on the Controlled Substance List. Please don't hesitate to reach out if you have any questions.

Thank you for your time,

Mark Lambert

January 29, 2024

Arkansas Department of Health
Center for Health Protection, Pharmacy Services Section
4815 W. Markham St.
Little Rock, AR 72205

RE: Re: Proposed changes in the Controlled Substance List Summary 002: "10 Xylazine. Xylazine is utilized in veterinarian medicine and would be included into Schedule III."

The Arkansas Farm Bureau Federation urges the Arkansas Department of Health to exempt commercially available xylazine, for veterinary use, from being listed as a Schedule III drug when being "dispensed or prescribed for, or administration to, a nonhuman species of a drug containing xylazine that has been approved by the Secretary of Health and Human Services under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A 260b)."

Xylazine is an essential tool for large animal veterinarians to humanely sedate animals for examination, diagnosis and treatment. Moving this drug to a Schedule III classification, without a veterinary exemption, would cause substantial harm to ranchers and negatively impact the safe and affordable care of their animals. Ranchers must utilize veterinarians to care for and diagnose livestock to ensure herd health and provide a safe and vibrant food system. The addition of xylazine as a schedule III drug, without a veterinary exemption, will burden veterinarians with unnecessary regulations and jeopardize ranchers' access to expert care of their animals. Currently, there are no other cost effective and practical alternatives to sedate large animals. Additionally, loss of access to xylazine will jeopardize the safety of veterinarians who rely on this drug to safely examine livestock, potentially causing a negative impact to animal and herd health within our state. The only acceptable alternatives would financially impact ranchers, who must now pay for far more expensive sedatives during veterinary examination, if those alternative medications are even available.

There are currently two pieces of federal legislation in committee that exempt the FDA-approved veterinary product and its use from scheduling and maintaining its prescription status: HR18369/S993 and HR4531.

While Arkansas Farm Bureau is aware of the illicit use of xylazine and the dangers it can pose to the public; it is important to note that the commercially available xylazine used by veterinary practitioners and livestock producers is a liquid injectable product, which cannot be used to mix with illicit street drugs.

We appreciate the opportunity to provide these comments and can be reached for any clarification and discussion needed.

Regards,

Mark Lambert
Director of State Affairs

Proposed Amendments to the List of Controlled Substances for the State of Arkansas
Arkansas Code Annotated § 5-64-201 through 5-64-216
Public Hearing held on January 23, 2024
Public comments made during the hearing.

Rule and Specific Information:	Individual/Group	Comments
Proposed Amendment(s) to the Controlled Substance List. All comments listed are in opposition to the addition of xylazine into Schedule III without an exemption for veterinarian use.	*Dr. Kate Williams, Companion Animal Veterinarian in Northwest Arkansas, Serves on Arkansas Veterinary Medical Association (AVMA) Board as American Veterinary Medical Association alternate delegate	Xylazine is "an important prescription veterinary sedative used to facilitate safe handling and treatment of large animals, primarily equine and cattle. Any changes to scheduling of xylazine in the state of Arkansas could potentially negatively impact veterinary access to the drug and limit what veterinarians can do for safe handling of cattle. The cattle and horse business in the state of Arkansas is a very large economic benefit to the state of Arkansas. Xylazine is used as a sedative for fractious and large animals and used for safe handling. Because it is not an opioid, it can be reversed, and the animals can be right back into the herd during post operative care." "We as veterinarians understand the pose to public health, but limiting veterinary access to this drug is critical and jeopardizes animal and human safety. On the legislative side and on the big picture side, there are two acts that are currently being proposed at the federal government side. One is the Combating Illicit Xylazine Act which is primarily targeted to create illicit xylazine as a Schedule III drug exempting veterinary use so it can continue

(*) An asterisk denotes the individual had provided a written public comment and made a verbal public comment at the public hearing held on January 23, 2024. This will reflect one comment received.

		as we are currently using it. Then there is the Support Act language which does the same thing, it schedules Xylazine as a Schedule III federally while exempting the use of the medication as legitimate use in veterinary medicine. Without congressional legislation, the AVMA is concerned that the DEA removes xylazine to schedule III without the veterinary exemption which will limit the access of this important drug to veterinary medicine. Without federal legislation, this results in a regulatory uniformity mismatch. Basically, states are trying to patchwork their listing of xylazine as a schedule III drug and acting before the federal government has an opportunity to schedule xylazine as a schedule III. The intent of these two legislative actions is to exempt veterinary use." "Xylazine is a liquid, comes directly through legitimate veterinary channels. It is an FDA approved veterinary use only bottle of liquid xylazine. What we use in veterinary medicine on the farms, in clinics, in zoos, in laboratory animals, in wildlife is the injectable version which comes in 50 ml bottles. That is not the source of the problem. The source of illicit xylazine is diversion of xylazine from the

		manufacturers. So, it's coming into Mexico, basically from overseas. So, the raw product is being manufactured illicitly or legally but is being diverted into the drug market and then that raw product, which is a powder form, is then being split into fentanyl and entering the illicit drug trade. So, I urge and encourage the ADH to consider the information that our team is about to present and consider exempting xylazine from a schedule III drug in the state of Arkansas while we wait for the federal government to actually schedule it as a Schedule III with the exemption for the states."
	*Dr. Everett Rogers, President of the Arkansas Veterinary Medical Association, practicing veterinarian for 49 years, has small animal practice in Jonesboro	Xylazine is "an indispensable tool particularly in the large animal section, for the use of cattle and horses for sure. These large animals can be very health threatening to their handlers, injuries can occur. On the other side of it, when we do minor surgical procedures on large animals, from a humane standpoint the xylazine does provide a mechanism to provide some pain relief during these minor surgical procedures." "The problem with Schedule III is it would require more paperwork, more bureaucracy involved with that. If a veterinarian had a particular client that was a large producer and had a large number of

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Proposed Amendments to the List of Controlled Substances for the State of Arkansas
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		horses or cattle, was well trained and responsible, if that veterinarian wanted to dispense a small quantity, maybe 5 cc, for them to use in their management procedures in their farms, having it Schedule III would eliminate this." "Where the problem is coming from is not from the veterinary practitioner out in the field, the problem is coming from the diversion of the powdered product before it is manufactured. Also, there is no compounding situation with this drug, all of our sources are coming directly from end stage manufacturers. There are probably only a couple of manufacturers producing xylazine now, there are some fears that is kind of a low volume drug for them and if this is scheduled, they might stop producing it. We are concerned about the lack of availability for the legitimate use of it in veterinary practice."
	Dr. Rob Conner, veterinarian of 34 years from Mountain Home with a mixed animal practice	"Xylazine is a product we use routinely on the farm for our horse clients as well as our food animal clients. We also use it historically occasionally in small animal practice when there is a lack of availability of analogous products. The risk for us as large animal practitioners, and speaking on behalf of the farmers and others, in those

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		applications, I have no other alternative. So, if you take that away as the product that I can use to sedate animals, to assist in their capture, control, or anesthesia, I have no analogous products to use. As a matter of safety, which is paramount on the farm, when dealing with large animals that tend to be fractious, it is certainly something that could put the public at higher risk." "Products that we use are small bottles of liquid and I'm told the nefarious use of xylazine is actually powder coming from other sources. So, I do think we are not putting the public as risk. We are very careful with those drugs. I do hold a DEA license, so I am very careful to not risk my license. Veterinarians can be trusted to protect the public from this drug. I do feel quite confident that this is something that should continue to be available as a prescription item. We do not sell bottles of this over the counter, this is something that we do totally control."
	Rodney Baker, lobbyist for the Arkansas Veterinarian Medical Association	"I've been asked by my friends at the Cattlemen's Association to share that they have filed a letter on this issue reflecting their concerns about losing xylazine as a prescription drug. They asked me to share that

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		with you. They couldn't be here today and send their apologies."
	*Mark Lambert, State Affairs Director with Farm Bureau	"We represent 180,000 farmers, ranchers, and rural Arkansans across Arkansas. The number one thing that everyone is concerned with is the safe and effective use of veterinary care. If veterinarians can't do their job and treat these animals in a safe and effective manner then that puts our farmers, our ranchers, our veterinarians, and everybody at risk with the loss of this product. Farm Bureau plans to submit comments on the rescheduling of xylazine to exempt our veterinarians so they can have safe and effective veterinary care for animals."

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