

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—119th Cong., 2d Sess.

S. 545

To prohibit certain uses of xylazine, and for other purposes.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by _____

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This title may be cited as the “Combating Illicit
5 Xylazine Act”.

6 **SEC. 2. DEFINITIONS.**

7 (a) IN GENERAL.—In this title, the term “xylazine”
8 has the meaning given the term in paragraph (61) of sec-
9 tion 102 of the Controlled Substances Act, as added by
10 subsection (b) of this section.

11 (b) CONTROLLED SUBSTANCES ACT.—Section 102 of
12 the Controlled Substances Act (21 U.S.C. 802) is amend-
13 ed by adding at the end the following:

1 “(61) The term ‘xylazine’ means the substance
2 xylazine, including its salts, isomers, and salts of isomers
3 whenever the existence of such salts, isomers, and salts
4 of isomers is possible.”.

5 **SEC. 3. ADDING XYLAZINE TO SCHEDULE III.**

6 Schedule III of section 202(c) of the Controlled Sub-
7 stances Act (21 U.S.C. 812) is amended by adding at the
8 end the following:

9 “(f) Unless specifically excepted or unless listed in
10 another schedule, any material, compound, mixture, or
11 preparation which contains any quantity of xylazine.”.

12 **SEC. 4. AMENDMENTS.**

13 (a) AMENDMENT.—Section 102 of the Controlled
14 Substances Act (21 U.S.C. 802) is amended by striking
15 paragraph (27) and inserting the following:

16 “(27)(A) Except as provided in subparagraph (B),
17 the term ‘ultimate user’ means a person who has lawfully
18 obtained, and who possesses, a controlled substance for
19 the use by the person or for the use of a member of the
20 household of the person or for an animal owned by the
21 person or by a member of the household of the person.

22 “(B)(i) In the case of xylazine, other than for a drug
23 product approved under subsection (b) or (j) of section
24 505 of the Federal Food, Drug, and Cosmetic Act (21
25 U.S.C. 355), the term ‘ultimate user’ means a person—

1 “(I) to whom xylazine was dispensed by—

2 “(aa) a veterinarian registered under this
3 Act; or

4 “(bb) a pharmacy registered under this
5 Act pursuant to a prescription of a veterinarian
6 registered under this Act; and

7 “(II) who possesses xylazine for—

8 “(aa) an animal owned by the person or by
9 a member of the household of the person;

10 “(bb) an animal under the care of the per-
11 son;

12 “(cc) use in government animal-control
13 programs authorized under applicable Federal,
14 State, Tribal, or local law; or

15 “(dd) use in wildlife programs authorized
16 under applicable Federal, State, Tribal, or local
17 law.

18 “(ii) In this subparagraph, the term ‘person’ in-
19 cludes—

20 “(I) a government agency or business where
21 animals are located; and

22 “(II) an employee or agent of an agency or
23 business acting within the scope of their employment
24 or agency.”.

1 (b) FACILITIES.—An entity that manufactures
2 xylazine, as of the date of enactment of this Act, shall
3 not be required to make capital expenditures necessary to
4 install the security standard required of schedule III of
5 the Controlled Substances Act (21 U.S.C. 801 et seq.) for
6 the purposes of manufacturing xylazine.

7 (c) LABELING.—The requirements related to label-
8 ing, packaging, and distribution logistics of a controlled
9 substance in schedule III of section 202(c) of the Con-
10 trolled Substances Act (21 U.S.C. 812(c)) shall not take
11 effect for xylazine until the date that is 1 year after the
12 date of enactment of this Act.

13 (d) PRACTITIONER REGISTRATION.—The require-
14 ments related to practitioner registration, inventory, and
15 recordkeeping of a controlled substance in schedule III of
16 section 202(c) of the Controlled Substances Act (21
17 U.S.C. 812(c)) shall not take effect for xylazine until the
18 date that is 60 days after the date of enactment of this
19 Act. A practitioner that has applied for registration during
20 the 60-day period beginning on the date of enactment of
21 this Act may continue their lawful activities until such ap-
22 plication is approved or denied.

23 (e) MANUFACTURER TRANSITION.—The Food and
24 Drug Administration and the Drug Enforcement Adminis-
25 tration shall facilitate and expedite the relevant manufac-

1 turer submissions or applications required by the place-
2 ment of xylazine on schedule III of section 202(c) of the
3 Controlled Substances Act (21 U.S.C. 812(c)).

4 (f) CLARIFICATION.—Nothing in this title, or the
5 amendments made by this title, shall be construed to re-
6 quire the registration of an ultimate user of xylazine under
7 the Controlled Substances Act (21 U.S.C. 801 et seq.) in
8 order to possess xylazine in accordance with subparagraph
9 (B) of section 102(27) of that Act (21 U.S.C. 802(27)),
10 as added by subsection (a) of this section.

11 **SEC. 5. ARCOS TRACKING.**

12 Section 307(i) of the Controlled Substances Act (21
13 U.S.C. 827(i)) is amended—

14 (1) in the matter preceding paragraph (1)—

15 (A) by inserting “or xylazine” after
16 “gamma hydroxybutyric acid”;

17 (B) by inserting “or 512” after “section
18 505”; and

19 (C) by inserting “respectively,” after “the
20 Federal Food, Drug, and Cosmetic Act,”; and

21 (2) in paragraph (6), by inserting “or xylazine”
22 after “gamma hydroxybutyric acid”.

23 **SEC. 6. SENTENCING COMMISSION.**

24 Pursuant to its authority under section 994(p) of title
25 28, United States Code, the United States Sentencing

1 Commission shall review and, if appropriate, amend its
2 sentencing guidelines, policy statements, and official com-
3 mentary applicable to persons convicted of an offense
4 under section 401 of the Controlled Substances Act (21
5 U.S.C. 841) or section 1010 of the Controlled Substances
6 Import and Export Act (21 U.S.C. 960) to provide appro-
7 priate penalties for offenses involving xylazine that are
8 consistent with the amendments made by this title. In car-
9 rying out this section, the Commission should consider the
10 common forms of xylazine as well as its use alongside
11 other scheduled substances.

12 **SEC. 7. REPORT TO CONGRESS ON XYLAZINE.**

13 (a) CONTROL REPORT.—

14 (1) IN GENERAL.—Not later than 30 days after
15 the date of enactment of this Act, the Attorney Gen-
16 eral, acting through the Administrator of the Drug
17 Enforcement Administration and in coordination
18 with the Secretary of Health and Human Services,
19 shall submit to Congress a report with an assess-
20 ment of the factors listed in section 201(c) of the
21 Controlled Substances Act (21 U.S.C. 811(c)) for
22 xylazine, which includes a scientific and medical
23 evaluation and recommendations from the Secretary
24 of Health and Human Services and a law enforce-

1 ment and abuse evaluation by the Drug Enforce-
2 ment Administration.

3 (2) REQUIREMENTS.—The report required
4 under paragraph (1) shall—

5 (A) include the full text of the scientific
6 and medical evaluation and recommendations
7 regarding whether xylazine should be controlled
8 as a controlled substance, submitted by the Sec-
9 retary of Health and Human Services to the
10 Attorney General pursuant to section 201(b) of
11 the Controlled Substances Act (21 U.S.C.
12 811(b)) on or before December 31, 2025; and

13 (B) be published on the websites of the
14 Department of Health and Human Services and
15 the Department of Justice.

16 (b) INITIAL REPORT.—Not later than 18 months
17 after the date of the enactment of this Act, the Attorney
18 General, acting through the Administrator of the Drug
19 Enforcement Administration and in coordination with the
20 Commissioner of Food and Drugs, shall submit to Con-
21 gress a report on the prevalence of illicit use of xylazine
22 in the United States and the impacts of such use, includ-
23 ing—

24 (1) where the drug is being diverted;

25 (2) where the drug is originating; and

1 (3) whether any analogues to xylazine, or re-
2 lated or derivative substances, exist and present a
3 substantial risk of abuse.

4 (c) ADDITIONAL REPORT.—Not later than 4 years
5 after the date of the enactment of this Act, the Attorney
6 General, acting through the Administrator of the Drug
7 Enforcement Administration and in coordination with the
8 Commissioner of Food and Drugs, shall submit to Con-
9 gress a report updating Congress on the prevalence and
10 proliferation of xylazine trafficking and misuse in the
11 United States.