

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—118th Cong., 2d Sess.

S. _____

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 Ms. CORTEZ MASTO

Viz:

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

3 **SECTION 1. SHORT TITLE.**

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

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) Illicit xylazine presents an urgent threat to
9 public health and safety.

10 (2) The proliferation of xylazine as an additive
11 to illicit drugs such as fentanyl and other narcotics
12 threatens to exacerbate the opioid public health
13 emergency.

1 (3) There is currently no drug approved by the
2 Food and Drug Administration to reverse the effects
3 of xylazine in humans.

4 (4) The adverse effects resulting from the use
5 of xylazine in humans, including depressed breathing
6 and heart rate and unconsciousness, necrosis, some-
7 times leading to amputation, and other permanent
8 physical health consequences have been observed in
9 humans using xylazine.

10 (5) The spread of illicit xylazine use has fol-
11 lowed geographic patterns seen in the spread of il-
12 licit fentanyl use, with proliferation encountered ini-
13 tially in the Northeastern United States and later
14 spreading south and west.

15 (6) Prompt action to control illicit xylazine will
16 help limit further proliferation of illicit xylazine, sav-
17 ing countless lives.

18 **SEC. 3. DEFINITIONS.**

19 (a) IN GENERAL.—In this Act, the term “xylazine”
20 has the meaning given the term in paragraph (60) of sec-
21 tion 102 of the Controlled Substances Act, as added by
22 subsection (b) of this section.

23 (b) CONTROLLED SUBSTANCES ACT.—Section 102 of
24 the Controlled Substances Act (21 U.S.C. 802) is amend-
25 ed—

1 (1) by redesignating the second paragraph (57)
2 (relating to serious drug felony) and paragraph (58)
3 as paragraphs (58) and (59), respectively; and

4 (2) by adding at the end the following:

5 “(60) The term ‘xylazine’ means the substance
6 xylazine, including its salts, isomers, and salts of
7 isomers whenever the existence of such salts, iso-
8 mers, and salts of isomers is possible.”.

9 **SEC. 4. ADDING XYLAZINE TO SCHEDULE III.**

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

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

16 **SEC. 5. AMENDMENTS.**

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

20 “(27)(A) Except as provided in subparagraph (B),
21 the term ‘ultimate user’ means a person who has lawfully
22 obtained, and who possesses, a controlled substance for
23 his own use or for the use of a member of his household
24 or for an animal owned by him or by a member of his
25 household.

1 “(B)(i) In the case of xylazine, other than for a drug
2 product approved under subsection (b) or (j) of section
3 505 of the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 355), the term ‘ultimate user’ means a person—

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

6 “(aa) a veterinarian registered under this
7 Act; or

8 “(bb) a pharmacy registered under this
9 Act pursuant to a prescription of a veterinarian
10 registered under this Act; and

11 “(II) who possesses xylazine for—

12 “(aa) an animal owned by him or by a
13 member of his household;

14 “(bb) an animal under his care;

15 “(cc) use in government animal-control
16 programs authorized under applicable Federal,
17 State, Tribal, or local law; or

18 “(dd) use in wildlife programs authorized
19 under applicable Federal, State, Tribal, or local
20 law.

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

23 “(I) a government agency or business where
24 animals are located; and

1 “(II) an employee or agent of an agency or
2 business acting within the scope of their employment
3 or agency.”.

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

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

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

1 (e) **MANUFACTURER TRANSITION.**—The Food and
2 Drug Administration and the Drug Enforcement Adminis-
3 tration shall facilitate and expedite the relevant manufac-
4 turer submissions or applications required by the place-
5 ment of xylazine on schedule III of section 202(c) of the
6 Controlled Substances Act (21 U.S.C. 812(c)).

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

14 **SEC. 6. ARCOS TRACKING.**

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

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

18 (A) by inserting “or xylazine” after
19 “gamma hydroxybutyric acid”;

20 (B) by inserting “or 512” after “section
21 505”; and

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

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

1 **SEC. 7. SENTENCING COMMISSION.**

2 Pursuant to its authority under section 994(p) of title
3 28, United States Code, the United States Sentencing
4 Commission shall review and, if appropriate, amend its
5 sentencing guidelines, policy statements, and official com-
6 mentary applicable to persons convicted of an offense
7 under section 401 of the Controlled Substances Act (21
8 U.S.C. 841) or section 1010 of the Controlled Substances
9 Import and Export Act (21 U.S.C. 960) to provide appro-
10 priate penalties for offenses involving xylazine that are
11 consistent with the amendments made by this Act. In car-
12 rying out this section, the Commission should consider the
13 common forms of xylazine as well as its use alongside
14 other scheduled substances.

15 **SEC. 8. REPORT TO CONGRESS ON XYLAZINE.**

16 (a) 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 (b) 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.