118TH CONGRESS 1ST SESSION

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

IN THE SENATE OF THE UNITED STATES

Ms. CORTEZ MASTO introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

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

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,

3 SECTION 1. SHORT TITLE.

4 This Act may be cited as the "Combating Illicit5 Xylazine Act".

6 SEC. 2. FINDINGS.

- 7 Congress finds the following:
- 8 (1) Illicit xylazine presents an urgent threat to9 public health and safety.
- 10 (2) The proliferation of xylazine as an additive11 to illicit drugs such as fentanyl and other narcotics

threatens to exacerbate the opioid public health
 emergency.
 (3) There is currently no drug approved by the

4 Food and Drug Administration to reverse the effects5 of xylazine in humans.

6 (4) The physical effects of use of xylazine in 7 humans can include depressed breathing and heart 8 rate, unconsciousness, and necrosis, sometimes lead-9 ing to amputation or other permanent physical 10 health consequences.

(5) The spread of illicit xylazine use has followed geographic patterns seen in the spread of recreational fentanyl use, with proliferation beginning
in the Northeastern United States and later spreading south and west.

16 (6) Prompt action to control illicit xylazine will
17 help limit further proliferation of illicit xylazine, sav18 ing countless lives.

19 SEC. 3. DEFINITIONS.

(a) IN GENERAL.—In this Act, the term "xylazine"
has the meaning given the term in paragraph (60) of section 102 of the Controlled Substances Act, as added by
subsection (b) of this section.

DISCUSSION DRAFT

3

(b) CONTROLLED SUBSTANCES ACT.—Section 102 of 1 2 the Controlled Substances Act (21 U.S.C. 802) is amend-3 ed— 4 (1) by redesignating the second paragraph (57)5 (relating to serious drug felony) and paragraph (58) 6 as paragraphs (58) and (59), respectively; and 7 (2) by adding at the end the following: "(60) The term 'xylazine' means any of the following 8 9 substances, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and 10 11 salts of isomers is possible within the specific chemical designation: 12 13 "(A) Xylazine. "(B) Xylazine-M (2,6Mich dimethylaniline). 14 "(C) Xylazine-M 15 (N-thiourea-2,6dimethylaniline). 16 17 "(D) Xylazine-M (sulfone-HO-) isomer 2. 18 "(E) Xylazine-M (HO-2,6-dimethylaniline iso-19 mer 1). "(F) Xylazine-M (HO-2,6-dimethylaniline iso-20 21 mer 2). 22 "(G) Xylazine M (oxo-). "(H) Xylazine-M (HO-) isomer 1. 23 24 "(I) Xylazine-M (HO-) isomer 1 glucuronide.

25 "(J) Xylazine-M (HO-) isomer 2.

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1	"(K) Xylazine-M (HO-) isomer 2 glucuronide.
2	"(L) Xylazine-M (HO-oxo-) isomer 1.
3	"(M) Xylazine-M (HO-oxo-) isomer 1 glu-
4	curonide.
5	"(N) Xylazine-M (HO-oxo-) isomer 2.
6	"(O) Xylazine-M (HO-oxo-) isomer 2 glu-
7	curonide.
8	"(P) Xylazine-M (sulfone).
9	"(Q) Xylazine-M (sulfone-HO-) isomer 1.
10	"(R) Any compound, mixture, or preparation
11	which contains any quantity of any of the substances
12	referred to in subparagraphs (A) through (Q).".
13	SEC. 4. UNLAWFUL DISTRIBUTION AND PENALTIES RELAT-
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13 14	ING TO XYLAZINE.
13 14 15	ING TO XYLAZINE. (a) Prohibited Acts A—Penalties.—
13 14 15 16	ING TO XYLAZINE. (a) Prohibited Acts A—Penalties.— (1) Controlled substances Act.—Section
 13 14 15 16 17 	ING TO XYLAZINE. (a) PROHIBITED ACTS A—PENALTIES.— (1) CONTROLLED SUBSTANCES ACT.—Section 401 of the Controlled Substances Act (21 U.S.C.
 13 14 15 16 17 18 	ING TO XYLAZINE. (a) PROHIBITED ACTS A—PENALTIES.— (1) CONTROLLED SUBSTANCES ACT.—Section 401 of the Controlled Substances Act (21 U.S.C. 841) is amended—
 13 14 15 16 17 18 19 	ING TO XYLAZINE. (a) PROHIBITED ACTS A—PENALTIES.— (1) CONTROLLED SUBSTANCES ACT.—Section 401 of the Controlled Substances Act (21 U.S.C. 841) is amended— (A) in subsection (a)(1), by inserting "or
 13 14 15 16 17 18 19 20 	ING TO XYLAZINE. (a) PROHIBITED ACTS A—PENALTIES.— (1) CONTROLLED SUBSTANCES ACT.—Section 401 of the Controlled Substances Act (21 U.S.C. 841) is amended— (A) in subsection (a)(1), by inserting "or xylazine for illicit uses under section 424" after
 13 14 15 16 17 18 19 20 21 	ING TO XYLAZINE. (a) PROHIBITED ACTS A—PENALTIES.— (1) CONTROLLED SUBSTANCES ACT.—Section 401 of the Controlled Substances Act (21 U.S.C. 841) is amended— (A) in subsection (a)(1), by inserting "or xylazine for illicit uses under section 424" after "controlled substance"; and
 13 14 15 16 17 18 19 20 21 22 	ING TO XYLAZINE. (a) PROHIBITED ACTS A—PENALTIES.— (1) CONTROLLED SUBSTANCES ACT.—Section 401 of the Controlled Substances Act (21 U.S.C. 841) is amended— (A) in subsection (a)(1), by inserting "or xylazine for illicit uses under section 424" after "controlled substance"; and (B) in subsection (b)(1)(E)(i), by inserting

1	(2) Controlled substances import and
2	EXPORT ACT.—Section 1010 of the Controlled Sub-
3	stances Import and Export Act (21 U.S.C. 960) is
4	amended—
5	(A) in subsection (a)—
6	(i) in paragraph (1), by inserting "or
7	xylazine for illicit uses under section 424"
8	after "controlled substance";
9	(ii) in paragraph (2), by inserting "or
10	xylazine for illicit uses under section 424"
11	after "controlled substance"; and
12	(iii) in paragraph (3), by inserting "or
13	xylazine for illicit uses under section 424"
14	after "controlled substance"; and
15	(B) in subsection $(b)(5)$, by inserting "or
16	the unlawful distribution of xylazine for illicit
17	uses under section 424" after "schedule III".
18	(b) Illicit Use and Distribution.—Part D of the
19	Controlled Substances Act (21 U.S.C. 401 et seq.) is
20	amended by adding at the end the following:
21	"SEC. 424. ILLICIT USE AND DISTRIBUTION OF XYLAZINE.
22	"(a) Illicit Use.—It is unlawful for any person to
23	engage in any of the following illicit uses of xylazine:
24	"(1) Any use in the human species.
25	"(2) Any use that is not a licit use.

1	"(b) LICIT USE.—Licit use of xylazine means—
2	"(1) any administration to nonhuman species—
3	"(A) of a drug containing xylazine that has
4	been approved by the Secretary of Health and
5	Human Services under section 512 of the Fed-
6	eral Food, Drug, and Cosmetic Act (21 U.S.C.
7	360b); or
8	"(B) that is permissible under section
9	512(a)(4) of the Federal Food, Drug, and Cos-
10	metic Act (21 U.S.C. 360b(a)(4));
11	((2) the manufacturing, importation, or use of
12	xylazine as an active pharmaceutical ingredient for
13	manufacturing an animal drug approved under sec-
14	tion 512 of the Federal Food, Drug, and Cosmetic
15	Act (21 U.S.C. 360b) or issued an investigation use
16	exemption under subsection (j) of such section 512;
17	"(3) the manufacturing, importation, or use of
18	a xylazine bulk chemical for pharmaceutical
19	compounding by licensed pharmacists or veterinar-
20	ians; or
21	"(4) another use approved or permissible under
22	the Federal Food, Drug, and Cosmetic Act $(21$
23	U.S.C. 301 et seq.).".

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1 SEC. 5. ARCOS TRACKING.

2	Section 307(i) of the Controlled Substances Act (21
3	U.S.C. 827) is amended—
4	(1) in the matter preceding paragraph (1) —
5	(A) by inserting "or xylazine" after
6	"gamma hydroxybutyric acid";
7	(B) by inserting "or 512" after "section
8	505''; and
9	(C) by inserting "respectively," after "the
10	Federal Food, Drug, and Cosmetic Act,"; and
11	(2) in paragraph (6), by inserting "or xylazine"
12	after ''gamma hydroxybutyric acid''.
13	SEC. 6. REPORT TO CONGRESS ON XYLAZINE.
14	(a) INITIAL REPORT.—Not later than 1 year after
15	the date of the enactment of this Act, the Attorney Gen-
16	eral, acting through the Administrator of the Drug En-
17	forcement Administration and in coordination with the
18	Commissioner of Food and Drugs, shall submit to Con-
10	
19	gress a report on the prevalence of illicit use of xylazine
20	gress a report on the prevalence of illicit use of xylazine in the United States and the impacts of such use, includ-
20	in the United States and the impacts of such use, includ-
20 21	in the United States and the impacts of such use, includ- ing—
20 21 22	in the United States and the impacts of such use, includ- ing— (1) where the drug is being diverted;

DISCUSSION DRAFT

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(4) whether and to what extent the illicit supply
 of xylazine derives from the licit supply chain; and
 (5) recommendations for Congress with respect
 to whether xylazine should be transferred to another
 schedule under part B of the Controlled Substances
 Act (21 U.S.C. 811 et seq.).

7 (b) ADDITIONAL REPORT.—Not later than 4 years 8 after the date of the enactment of this Act, the Attorney 9 General, acting through the Administrator of the Drug 10 Enforcement Administration and in coordination with the Commissioner of Food and Drugs, shall submit to Con-11 12 gress a report updating Congress on the prevalence of 13 xylazine trafficking, misuse, and proliferation in the United States, including recommendations for Congress 14 15 with respect to whether xylazine should be transferred to another schedule under part B of the Controlled Sub-16 17 stances Act (21 U.S.C. 811 et seq.) or removed from 18 schedule III of such part.

(c) DEFINITION.—In this section, the term "illicit
use" means any use described in section 424 of the Controlled Substances Act, as added by section 3 of this Act.

22 SEC. 7. DECLARATION OF EMERGING THREAT.

Congress declares illicit xylazine use an emergingdrug threat, as defined in section 702 of the Office of Na-

- 1 tional Drug Control Policy Reauthorization Act of 1998
- $2~(21~\mathrm{U.S.C.}~1701),$ in the United States.