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:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This title may be cited as the ''Combating Illicit Xylazine Act''.

SEC. 2. DEFINITIONS.

(a) IN GENERAL.—In this title, the term ''xylazine'' has the meaning given the term in paragraph (61) of section 102 of the Controlled Substances Act, as added by subsection (b) of this section.

(b) CONTROLLED SUBSTANCES ACT.—Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended by adding at the end the following:

''(61) The term 'xylazine' means the substance xylazine, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible.''.

SEC. 3. ADDING XYLAZINE TO SCHEDULE III.

Schedule III of section 202(c) of the Controlled Substances Act (21 U.S.C. 812) is amended by adding at the end the following:

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

SEC. 4. AMENDMENTS.

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

''(27)(A) Except as provided in subparagraph (B), the term 'ultimate user' means a person who has lawfully obtained, and who possesses, a controlled substance for the use by the person or for the use of a member of the household of the person or for an animal owned by the person or by a member of the household of the person.

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

''(I) to whom xylazine was dispensed by—

''(aa) a veterinarian registered under this Act; or

''(bb) a pharmacy registered under this Act pursuant to a prescription of a veterinarian registered under this Act; and

''(II) who possesses xylazine for—

''(aa) an animal owned by the person or by a member of the household of the person;

''(bb) an animal under the care of the person;

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

''(dd) use in wildlife programs authorized under applicable Federal, State, Tribal, or local law.

''(ii) In this subparagraph, the term 'person' includes—

''(I) a government agency or business where animals are located; and

''(II) an employee or agent of an agency or business acting within the scope of their employment or agency.''.

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

(c) LABELING.—The requirements related to labeling, packaging, and distribution logistics of a controlled substance in schedule III of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) shall not take effect for xylazine until the date that is 1 year after the date of enactment of this Act.

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

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

turer submissions or applications required by the placement of xylazine on schedule III of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)).

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

SEC. 5. ARCOS TRACKING.

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

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

(A) by inserting ''or xylazine'' after ''gamma hydroxybutyric acid'';

(B) by inserting ''or 512'' after ''section 505''; and

(C) by inserting ''respectively,'' after ''the Federal Food, Drug, and Cosmetic Act,''; and

(2) in paragraph (6), by inserting ''or xylazine'' after ''gamma hydroxybutyric acid''.

SEC. 6. SENTENCING COMMISSION.

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

Commission shall review and, if appropriate, amend its sentencing guidelines, policy statements, and official commentary applicable to persons convicted of an offense under section 401 of the Controlled Substances Act (21 U.S.C. 841) or section 1010 of the Controlled Substances Import and Export Act (21 U.S.C. 960) to provide appropriate penalties for offenses involving xylazine that are consistent with the amendments made by this title. In carrying out this section, the Commission should consider the common forms of xylazine as well as its use alongside other scheduled substances.

SEC. 7. REPORT TO CONGRESS ON XYLAZINE.

(a) CONTROL REPORT.—Not later than 1 year after the date of enactment of this Act, the Attorney General, acting through the Administrator of the Drug Enforcement Administration and in coordination with the Secretary of Health and Human Services, shall submit to Congress a report with an assessment of the factors listed in section 201(c) of the Controlled Substances Act (21 U.S.C. 811(c)) for xylazine, which includes a scientific and medical evaluation and recommendations from the Secretary of Health and Human Services and a law enforcement and abuse evaluation by the Drug Enforcement Administration.

(b) INITIAL REPORT.—Not later than 18 months after the date of the enactment of this Act, the Attorney General, acting through the Administrator of the Drug Enforcement Administration and in coordination with the Commissioner of Food and Drugs, shall submit to Congress a report on the prevalence of illicit use of xylazine in the United States and the impacts of such use, including—

(1) where the drug is being diverted;

(2) where the drug is originating; and

(3) whether any analogues to xylazine, or related or derivative substances, exist and present a substantial risk of abuse.

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