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Representative Webster

Cosponsors: Representatives Setzer, Stebelton, Wagner, Williams, S., Schindel, McGregor, J., Fessler, Evans, Seitz, Latta, Yuko, Koziura, Coley, Combs, Collier, Fende, Peterson, Heard, Ujvagi, Hughes, Reinhard, Letson, Otterman, Williams, B., Uecker

A B I L L

To amend sections 3715.521, 3715.55, and 3715.63 and to enact sections 3715.88, 3715.89, 3715.90, 3715.91, and 3715.92 of the Revised Code to permit pharmacy schools to accept for instructional purposes donations of certain dangerous drugs, including expired drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 3715.521, 3715.55, and 3715.63 be amended and sections 3715.88, 3715.89, 3715.90, 3715.91, and 3715.92 of the Revised Code be enacted to read as follows:

Sec. 3715.521. No person shall sell, offer for sale, or deliver at retail or to the consumer, any of the following:

(A) Any drug after the expiration date required by 21 C.F.R. 211.137 <u>except pursuant to sections 3715.88 to 3715.92 of the Revised Code</u>;

(B) Any infant formula after the "use by" date required by 21

C.F.R. 107.20;

(C) Any baby food after any expiration date, "use by" date, or sale date required by state or federal law or marked on the container by the manufacturer, processor, or packager.

Sec. 3715.55. (A) As used in this section, "expired" means:

(1) In the case of a drug, that the expiration date required by 21 C.F.R. 211.137 has passed;

(2) In the case of infant formula, the "use by" date required by 21 C.F.R. 107.20 has passed;

(3) In the case of baby food, that any expiration date, "use by" date, or sale date established by state or federal law or marked on the container by the manufacturer, processor, or packager has passed.

(B) ~~Whenever~~ Except as otherwise provided in this division, whenever the director of agriculture or the state board of pharmacy finds or has cause to believe, that any food, drug, device, or cosmetic is adulterated, or so misbranded as to be dangerous or fraudulent, within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, or that a drug, infant formula, or baby food is expired, the director or board shall affix to the article a tag or other appropriate marking, giving notice that the article is, or is suspected of being, adulterated, misbranded, or expired and has been detained or embargoed, and warning all persons not to remove or dispose of the article by sale or otherwise until permission for removal or disposal is given by the director or the board or the court. No person may remove or dispose of a detained or embargoed article by sale or otherwise without such permission. This division does not apply to expired drugs donated pursuant to sections 3715.88 to 3715.92 of the Revised Code.

(C) When an article detained or embargoed has been found by the director or board to be adulterated, misbranded, or expired, the director or board shall petition the municipal or county court in whose jurisdiction the article is detained or embargoed for an order for condemnation of the article. When the director or the board has not found within ten days that an article so detained or embargoed is adulterated, misbranded, or expired, the director or board shall remove the tag or other marking.

(D) If the court finds that a detained or embargoed article is adulterated, misbranded, or expired, the article shall, after entry of the decree, be destroyed at the expense of the claimant thereof, under the supervision of the director or the board, and all court costs, fees, storage, and other proper expenses shall be taxed against the claimant of the article or the claimant's agent; provided, that when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that the article shall be so labeled or processed, has been executed, may by order direct that the article be delivered to the claimant thereof for labeling or processing under the supervision of the director or the board. The expense of supervision shall be paid by the claimant. The bond shall be returned to the claimant of the article on representation to the court by the director or the board that the article is no longer in violation of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, and that the expenses of supervision have been paid.

(E) Whenever the director finds in any room, building, vehicle of transportation, or other structure, any meat, ~~sea food~~ seafood, poultry, vegetable, fruit, or other perishable articles that are unsound, or contain any filthy, decomposed, or putrid substance, or that may be poisonous or deleterious to health or

otherwise unsafe, the articles are declared to be a nuisance, and the director shall forthwith condemn or destroy the articles, or in any other manner render the articles unsalable as human food.

Sec. 3715.63. (A) A drug or device is adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if any of the following apply:

~~(A)~~(1) It consists, in whole or in part, of any filthy, putrid, or decomposed substance.

~~(B)~~(2) It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

~~(C)~~(3) It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

~~(D)~~(4) It is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch certified under authority of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended.

~~(E)~~(5) It purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendiums, or in the absence or inadequacy of such tests or methods of assay, those prescribed under the authority of the "Federal Food, Drug, and Cosmetic Act." A drug recognized in the compendiums is not adulterated under this division because it differs from the standard of strength,

quality, or purity set forth for that drug in the compendiums, if the difference in strength, quality, or purity is plainly stated on its label. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia and national formulary.

~~(F)~~(6) It is not subject to the provisions of division ~~(E)~~(A)(5) of this section, and its strength differs from or its purity or quality falls below that which it purports or is represented to possess.

~~(G)~~(7) It is a drug and any substance has been:

~~(1)~~(a) Mixed or packed with the drug so as to reduce the drug's quality or strength;

~~(2)~~(b) Substituted wholly or in part for the drug.

(B) An expired drug is not adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code if the drug is donated pursuant to sections 3715.88 to 3715.92 of the Revised Code.

Sec. 3715.88. As used in this section and in sections 3715.89 to 3715.92 of the Revised Code:

(A) "Expired" has the same meaning as in section 3715.55 of the Revised Code.

(B) "National drug code number" means the number registered for a drug pursuant to the listing system established by the United States food and drug administration under the "Drug Listing

Act of 1972," 86 Stat. 559, 21 U.S.C. 360, as amended.

(C) "Pharmacy school" means a school, college, university, or other educational institution that operates a pharmacy program recognized and approved by the state board of pharmacy.

(D) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(E) "Manufacturer of dangerous drugs," "terminal distributor of dangerous drugs," and "wholesale distributor of dangerous drugs" have the same meanings as in section 4729.01 of the Revised Code.

Sec. 3715.89. (A) Subject to divisions (B) and (C) of this section, any manufacturer of dangerous drugs, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs may donate a dangerous drug, including a dangerous drug that has expired, to a pharmacy school.

(B) A dangerous drug donation to a pharmacy school shall meet all of the following requirements:

(1) The dangerous drug is not a controlled substance.

(2) Each container in which a dangerous drug is donated contains a single national drug code number of that drug and no other drugs.

(3) If the dangerous drug is of a type that deteriorates with time, the container in which the drug is contained is plainly marked with the drug's expiration date.

(C) A dangerous drug donation to a pharmacy school shall be accompanied by a form signed by a representative of the manufacturer, terminal distributor, or wholesale distributor donating the drug. On delivery, a representative of the pharmacy school accepting the drug donation shall also sign the form. The form shall do both of the following:

(1) Confirm the acceptance of the dangerous drug donation by the pharmacy school;

(2) Confirm that both the manufacturer, terminal distributor, or wholesale distributor donating the dangerous drug and the pharmacy school accepting the donation understand the immunity provisions of section 3719.92 of the Revised Code.

Sec. 3715.90. (A) A pharmacy school may accept a donation of a dangerous drug if the donation is made in accordance with section 3715.89 of the Revised Code.

(B) All of the following apply to a dangerous drug donated to a pharmacy school:

(1) The dangerous drug shall be used solely for instructional purposes.

(2) The dangerous drug shall not be sold or transferred for consideration of any kind.

(3) In accordance with 21 C.F.R. 201.125, the dangerous drug shall not be used for a clinical use. "Clinical use" includes the drug being furnished to a human or animal with the intent or understanding that the human or animal will ingest or otherwise absorb the drug into the human's or animal's body.

Sec. 3715.91. The state board of pharmacy shall, in accordance with Chapter 119. of the Revised Code, adopt rules as necessary to give effect to sections 3715.89 and 3715.90 of the Revised Code.

Sec. 3715.92. The state board of pharmacy, any manufacturer of dangerous drugs, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs that in good faith donates a dangerous drug under section 3715.89 of the Revised Code, and any pharmacy school that accepts a dangerous drug

donation under section 3715.90 of the Revised Code, shall not, in the absence of bad faith, be subject to any of the following for matters related to the donation or acceptance of the drug: criminal prosecution; liability in tort or other civil action for injury, death, or loss to person or property; or professional liability.

Section 2. That existing sections 3715.521, 3715.55, and 3715.63 of the Revised Code are hereby repealed.