

As Introduced

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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**

A B I L L

To amend sections 3715.521, 3715.55, and 3715.63 and 1
to enact sections 3715.88, 3715.89, 3715.90, 2
3715.91, and 3715.92 of the Revised Code to permit 3
pharmacy schools to accept for instructional 4
purposes donations of certain dangerous drugs, 5
including expired drugs. 6

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

Section 1. That sections 3715.521, 3715.55, and 3715.63 be 7
amended and sections 3715.88, 3715.89, 3715.90, 3715.91, and 8
3715.92 of the Revised Code be enacted to read as follows: 9

Sec. 3715.521. No person shall sell, offer for sale, or 10
deliver at retail or to the consumer, any of the following: 11

(A) Any drug after the expiration date required by 21 C.F.R. 12
211.137 except pursuant to sections 3715.88 to 3715.92 of the 13
Revised Code; 14

(B) Any infant formula after the "use by" date required by 21 15
C.F.R. 107.20; 16

(C) Any baby food after any expiration date, "use by" date, 17
or sale date required by state or federal law or marked on the 18
container by the manufacturer, processor, or packager. 19

Sec. 3715.55. (A) As used in this section, "expired" means: 20

(1) In the case of a drug, that the expiration date required 21
by 21 C.F.R. 211.137 has passed; 22

(2) In the case of infant formula, the "use by" date required 23
by 21 C.F.R. 107.20 has passed; 24

(3) In the case of baby food, that any expiration date, "use 25
by" date, or sale date established by state or federal law or 26
marked on the container by the manufacturer, processor, or 27
packager has passed. 28

(B) ~~Whenever~~ Except as otherwise provided in this division, 29
whenever the director of agriculture or the state board of 30
pharmacy finds or has cause to believe, that any food, drug, 31
device, or cosmetic is adulterated, or so misbranded as to be 32
dangerous or fraudulent, within the meaning of sections 3715.01 33
and 3715.52 to 3715.72 of the Revised Code, or that a drug, infant 34
formula, or baby food is expired, the director or board shall 35
affix to the article a tag or other appropriate marking, giving 36
notice that the article is, or is suspected of being, adulterated, 37
misbranded, or expired and has been detained or embargoed, and 38
warning all persons not to remove or dispose of the article by 39
sale or otherwise until permission for removal or disposal is 40
given by the director or the board or the court. No person may 41
remove or dispose of a detained or embargoed article by sale or 42
otherwise without such permission. This division does not apply to 43
expired drugs donated pursuant to sections 3715.88 to 3715.92 of 44
the Revised Code. 45

(C) When an article detained or embargoed has been found by 46

the director or board to be adulterated, misbranded, or expired, 47
the director or board shall petition the municipal or county court 48
in whose jurisdiction the article is detained or embargoed for an 49
order for condemnation of the article. When the director or the 50
board has not found within ten days that an article so detained or 51
embargoed is adulterated, misbranded, or expired, the director or 52
board shall remove the tag or other marking. 53

(D) If the court finds that a detained or embargoed article 54
is adulterated, misbranded, or expired, the article shall, after 55
entry of the decree, be destroyed at the expense of the claimant 56
thereof, under the supervision of the director or the board, and 57
all court costs, fees, storage, and other proper expenses shall be 58
taxed against the claimant of the article or the claimant's agent; 59
provided, that when the adulteration or misbranding can be 60
corrected by proper labeling or processing of the article, the 61
court, after entry of the decree and after such costs, fees, and 62
expenses have been paid and a good and sufficient bond, 63
conditioned that the article shall be so labeled or processed, has 64
been executed, may by order direct that the article be delivered 65
to the claimant thereof for labeling or processing under the 66
supervision of the director or the board. The expense of 67
supervision shall be paid by the claimant. The bond shall be 68
returned to the claimant of the article on representation to the 69
court by the director or the board that the article is no longer 70
in violation of sections 3715.01 and 3715.52 to 3715.72 of the 71
Revised Code, and that the expenses of supervision have been paid. 72

(E) Whenever the director finds in any room, building, 73
vehicle of transportation, or other structure, any meat, ~~sea food~~ 74
seafood, poultry, vegetable, fruit, or other perishable articles 75
that are unsound, or contain any filthy, decomposed, or putrid 76
substance, or that may be poisonous or deleterious to health or 77
otherwise unsafe, the articles are declared to be a nuisance, and 78

the director shall forthwith condemn or destroy the articles, or 79
in any other manner render the articles unsalable as human food. 80

Sec. 3715.63. (A) A drug or device is adulterated within the 81
meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised 82
Code, if any of the following apply: 83

~~(A)~~(1) It consists, in whole or in part, of any filthy, 84
putrid, or decomposed substance. 85

~~(B)~~(2) It has been produced, processed, prepared, packed, or 86
held under unsanitary conditions whereby it may have been 87
contaminated with filth, or whereby it may have been rendered 88
injurious to health. 89

~~(C)~~(3) It is a drug and its container is composed, in whole 90
or in part, of any poisonous or deleterious substance that may 91
render the contents injurious to health. 92

~~(D)~~(4) It is a drug and it bears or contains, for purposes of 93
coloring only, a coal-tar color other than one from a batch 94
certified under authority of the "Federal Food, Drug, and Cosmetic 95
Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended. 96

~~(E)~~(5) It purports to be or is represented as a drug the name 97
of which is recognized in the United States pharmacopoeia and 98
national formulary, or any supplement to them, and its strength 99
differs from or its quality or purity falls below the standard set 100
forth in those compendiums. A determination as to strength, 101
quality, or purity shall be made in accordance with the tests or 102
methods of assay set forth in the compendiums, or in the absence 103
or inadequacy of such tests or methods of assay, those prescribed 104
under the authority of the "Federal Food, Drug, and Cosmetic Act." 105
A drug recognized in the compendiums is not adulterated under this 106
division because it differs from the standard of strength, 107
quality, or purity set forth for that drug in the compendiums, if 108

the difference in strength, quality, or purity is plainly stated 109
on its label. Whenever a drug is recognized in both the 110
homoeopathic pharmacopoeia of the United States and in the United 111
States pharmacopoeia and national formulary, including their 112
supplements, it shall be subject to the requirements of the United 113
States pharmacopoeia and national formulary unless it is labeled 114
and offered for sale as a homoeopathic drug, in which case it 115
shall be subject to the provisions of the homoeopathic 116
pharmacopoeia of the United States and not to those of the United 117
States pharmacopoeia and national formulary. 118

~~(F)~~(6) It is not subject to the provisions of division 119
~~(E)~~(A)(5) of this section, and its strength differs from or its 120
purity or quality falls below that which it purports or is 121
represented to possess. 122

~~(G)~~(7) It is a drug and any substance has been: 123

~~(1)~~(a) Mixed or packed with the drug so as to reduce the 124
drug's quality or strength; 125

~~(2)~~(b) Substituted wholly or in part for the drug. 126

(B) An expired drug is not adulterated within the meaning of 127
sections 3715.01 and 3715.52 to 3715.72 of the Revised Code if the 128
drug is donated pursuant to sections 3715.88 to 3715.92 of the 129
Revised Code. 130

Sec. 3715.88. As used in this section and in sections 3715.89 131
and 3715.90 of the Revised Code: 132

(A) "Expired" has the same meaning as in section 3715.55 of 133
the Revised Code. 134

(B) "National drug code number" means the number registered 135
for a drug pursuant to the listing system established by the 136
United States food and drug administration under the "Drug Listing 137
Act of 1972," 86 Stat. 559, 21 U.S.C. 360, as amended. 138

(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. 139
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(D) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code. 142
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Sec. 3715.89. (A) Subject to divisions (B) and (C) of this section, any person or entity may donate a dangerous drug, including a dangerous drug that has expired, to a pharmacy school. 144
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(B) A dangerous drug donation to a pharmacy school shall meet all of the following requirements: 147
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(1) The dangerous drug is not a controlled substance. 149

(2) Each container in which a dangerous drug is donated contains a single national drug code number of that drug and no other drugs. 150
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(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. 153
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(C) A dangerous drug donation to a pharmacy school shall be accompanied by a form signed by a representative of the person or entity 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: 156
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(1) Confirm the acceptance of the dangerous drug donation by the pharmacy school; 161
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(2) Confirm that both the person or entity donating the dangerous drug and the pharmacy school accepting the donation understand the immunity provisions of section 3719.92 of the Revised Code. 163
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Sec. 3715.90. (A) A pharmacy school may accept a donation of 167

a dangerous drug if the donation is made in accordance with 168
section 3715.89 of the Revised Code. 169

(B) All of the following apply to a dangerous drug donated to 170
a pharmacy school: 171

(1) The dangerous drug shall be used solely for instructional 172
purposes. 173

(2) The dangerous drug shall not be sold or transferred for 174
consideration of any kind. 175

(3) In accordance with 21 C.F.R. 201.125, the dangerous drug 176
shall not be used for a clinical use. "Clinical use" includes the 177
drug being furnished to a human or animal with the intent or 178
understanding that the human or animal will ingest or otherwise 179
absorb the drug into the human's or animal's body. 180

Sec. 3715.91. The state board of pharmacy shall, in 181
accordance with Chapter 119. of the Revised Code, adopt rules as 182
necessary to give effect to sections 3715.89 and 3715.90 of the 183
Revised Code. 184

Sec. 3715.92. The state board of pharmacy, the director of 185
health, any person or entity that in good faith donates a 186
dangerous drug under section 3715.89 of the Revised Code, and any 187
pharmacy school that accepts a dangerous drug donation under 188
section 3715.90 of the Revised Code, shall not, in the absence of 189
bad faith, be subject to any of the following for matters related 190
to the donation or acceptance of the drug: criminal prosecution; 191
liability in tort or other civil action for injury, death, or loss 192
to person or property; or professional liability. 193

Section 2. That existing sections 3715.521, 3715.55, and 194
3715.63 of the Revised Code are hereby repealed. 195