

By Senator Polsky

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A bill to be entitled

An act relating to the testing of cosmetics on animals; providing a short title; amending s. 499.005, F.S.; providing that it is unlawful for a person to manufacture, repackage, sell, hold, or offer for sale cosmetics that have been tested on animals as part of the manufacturing process; creating s. 499.0095, F.S.; prohibiting manufacturers from using animal testing as part of the cosmetics manufacturing process; prohibiting manufacturers from repackaging, selling, holding, or offering for sale cosmetics that have been tested on animals; providing exceptions; providing that manufacturers, upon issuance of a cosmetic manufacturer permit, consent to specified inspections by the Department of Business and Professional Regulation; providing a penalty for refusal to allow such inspections; requiring holders of such permits to submit to the department certain written documentation by a specified date each year; providing for criminal penalties; providing an administrative penalty; providing for a cause of action by the department; authorizing the department to adopt rules; amending ss. 499.01, 499.003, and 499.0051, F.S.; conforming a provision and cross-references to changes made by the act; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. This act may be cited as the "Sickles High

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30 School Ought to be a Law Cosmetic Animal Testing Act of 2026."

31 Section 2. Present subsections (5) through (29) of section  
32 499.005, Florida Statutes, are redesignated as subsections (6)  
33 through (30), respectively, and a new subsection (5) is added to  
34 that section, to read:

35 499.005 Prohibited acts.—It is unlawful for a person to  
36 perform or cause the performance of any of the following acts in  
37 this state:

38 (5) The manufacture, repackaging, sale, holding, or  
39 offering for sale of cosmetics that have been tested on animals  
40 as part of the manufacturing process.

41 Section 3. Section 499.0095, Florida Statutes, is created  
42 to read:

43 499.0095 Cosmetics tested on animals prohibited.—

44 (1) (a) A manufacturer may not use animal testing as part of  
45 the process to manufacture cosmetics.

46 (b) A manufacturer may not repackage, sell, hold, or offer  
47 for sale cosmetics that have been tested on animals.

48 (2) This section does not apply to the manufacturing of  
49 cosmetics, or the repackaging, selling, holding, or offering for  
50 sale of cosmetics, if animal testing of such products is:

51 (a) Required by federal law.

52 (b) Conducted to comply with the requirements of a foreign  
53 regulatory authority or the laws of any foreign country.

54 (c) Conducted for purposes other than cosmetic purposes,  
55 and the data collected from such testing is not used to evaluate  
56 the safety or effectiveness of cosmetics sold in this state.

57 (3) (a) A manufacturer, upon issuance of a cosmetic  
58 manufacturer permit pursuant to s. 499.01(2)(p), consents to the

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department's authorized officer or employee entering and inspecting the premises on an annual basis to determine compliance with this section and department rules, as applicable. A refusal to allow an authorized officer or employee of the department to enter the premises or to conduct an inspection is a violation of s. 499.005(7) and is grounds for disciplinary action pursuant to s. 499.066.

(b) By January 31 of each year, each holder of a cosmetic manufacturer permit issued pursuant to s. 499.01 shall submit to the department written documentation to verify his or her compliance with this section.

(4)(a) A person who violates this section or s. 499.005 commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

(b) In addition to the criminal penalties imposed in paragraph (a), a person who violates this section is subject to an administrative penalty of \$5,000 for each violation. Each day the violation continues constitutes a separate violation. Penalties collected pursuant to this paragraph are payable to the department to be deposited into the Professional Regulation Trust Fund for the sole purpose of carrying out this section.

(c) In addition to other penalties, the department may institute such suits or other legal proceedings as are required to enforce this section pursuant to s. 499.066.

(5) The department may adopt rules to implement this section.

Section 4. Paragraph (p) of subsection (2), subsection (3), and paragraph (g) of subsection (4) of section 499.01, Florida Statutes, are amended to read:

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499.01 Permits.—

(2) The following permits are established:

(p) *Cosmetic manufacturer permit.*—A cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit under this paragraph. A person who manufactures cosmetics and has annual gross sales of \$25,000 or less is exempt from the permit requirements of this paragraph, unless such person manufacturers cosmetics using animal testing as part of the manufacturing process. Upon request, an exempt cosmetic manufacturer must provide to the department written documentation to verify his or her annual gross sales, including all sales of cosmetic products at any location, regardless of the types of products sold or the number of persons involved in the operation.

1. An exempt cosmetic manufacturer may only:

a. Sell prepackaged cosmetics affixed with a label containing information required by the United States Food and Drug Administration.

b. Manufacture and sell cosmetics that are soaps, not otherwise exempt from the definition of cosmetics, lotions, moisturizers, and creams.

c. Sell cosmetics that are not adulterated or misbranded in accordance with 21 U.S.C. ss. 361 and 362.

d. Sell cosmetic products that are stored on the premises of the cosmetic manufacturing operation.

2. Each unit of cosmetics manufactured under this paragraph

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117 must contain, in contrasting color and not less than 10-point  
118 type, the following statement: "Made by a manufacturer exempt  
119 from Florida's cosmetic manufacturing permit requirements."

120 3. The department may investigate any complaint which  
121 alleges that an exempt cosmetic manufacturer has violated an  
122 applicable provision of this chapter or a rule adopted under  
123 this chapter. The department's authorized officer or employee  
124 may enter and inspect the premises of an exempt cosmetic  
125 manufacturer to determine compliance with this chapter and  
126 department rules, as applicable. A refusal to permit an  
127 authorized officer or employee of the department to enter the  
128 premises or to conduct an inspection is a violation of s.  
129 499.005(7) ~~s. 499.005(6)~~ and is grounds for disciplinary action  
130 pursuant to s. 499.066.

131 4. This paragraph does not exempt any person from any state  
132 or federal tax law, rule, regulation, or certificate or from any  
133 county or municipal law or ordinance that applies to cosmetic  
134 manufacturing.

135 (3) A nonresident prescription drug manufacturer permit is  
136 not required for a manufacturer to distribute a prescription  
137 drug active pharmaceutical ingredient that it manufactures to a  
138 prescription drug manufacturer permitted in this state intended  
139 for research and development and not for resale or human use  
140 other than lawful clinical trials and biostudies authorized and  
141 regulated by federal law. A manufacturer claiming to be exempt  
142 from the permit requirements of this subsection and the  
143 prescription drug manufacturer purchasing and receiving the  
144 active pharmaceutical ingredient shall comply with the  
145 recordkeeping requirements of s. 499.0121(6). The prescription

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146 drug manufacturer purchasing and receiving the active  
147 pharmaceutical ingredient shall maintain on file a record of the  
148 FDA registration number; if available, the out-of-state license,  
149 permit, or registration number; and, if available, a copy of the  
150 most current FDA inspection report, for all manufacturers from  
151 whom they purchase active pharmaceutical ingredients under this  
152 section. The failure to comply with the requirements of this  
153 subsection, or rules adopted by the department to administer  
154 this subsection, for the purchase of prescription drug active  
155 pharmaceutical ingredients is a violation of s. 499.005(15) ~~s.~~  
156 ~~499.005(14)~~, and a knowing failure is a violation of s.  
157 499.0051(3).

158 (a) The immediate package or container of a prescription  
159 drug active pharmaceutical ingredient distributed into the state  
160 that is intended for research and development under this  
161 subsection shall bear a label prominently displaying the  
162 statement: "Caution: Research and Development Only—Not for  
163 Manufacturing, Compounding, or Resale."

164 (b) A prescription drug manufacturer that obtains a  
165 prescription drug active pharmaceutical ingredient under this  
166 subsection for use in clinical trials and or biostudies  
167 authorized and regulated by federal law must create and maintain  
168 records detailing the specific clinical trials or biostudies for  
169 which the prescription drug active pharmaceutical ingredient was  
170 obtained.

171 (4)

172 (g) The department may adopt rules to administer this  
173 subsection which are necessary for the protection of the public  
174 health, safety, and welfare. Failure to comply with the

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requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(15) ~~s. 499.005(14)~~, and a knowing failure is a violation of s. 499.0051(3).

Section 5. Paragraphs (a) and (b) of subsection (48) of section 499.003, Florida Statutes, are amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(48) "Wholesale distribution" means the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient, but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(22) ~~s. 499.005(21)~~ if such activity is conducted in accordance with s. 499.01(2)(h):

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The distribution of a prescription drug or an offer to distribute a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The distribution of a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies

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of a person or an organization, whether by ownership of stock,  
by voting rights, by contract, or otherwise.

4. The distribution of a prescription drug from or for any  
federal, state, or local government agency or any entity  
eligible to purchase prescription drugs at public health  
services prices pursuant to Pub. L. No. 102-585, s. 602 to a  
contract provider or its subcontractor for eligible patients of  
the agency or entity under the following conditions:

a. The agency or entity must obtain written authorization  
for the distribution of a prescription drug under this  
subparagraph from the Secretary of Business and Professional  
Regulation or his or her designee.

b. The contract provider or subcontractor must be  
authorized by law to administer or dispense prescription drugs.

c. In the case of a subcontractor, the agency or entity  
must be a party to and execute the subcontract.

d. The contract provider and subcontractor must maintain  
and produce immediately for inspection all records of movement  
or transfer of all the prescription drugs belonging to the  
agency or entity, including, but not limited to, the records of  
receipt and disposition of prescription drugs. Each contractor  
and subcontractor dispensing or administering these drugs must  
maintain and produce records documenting the dispensing or  
administration. Records that are required to be maintained  
include, but are not limited to, a perpetual inventory itemizing  
drugs received and drugs dispensed by prescription number or  
administered by patient identifier, which must be submitted to  
the agency or entity quarterly.

e. The contract provider or subcontractor may administer or



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233 dispense the prescription drugs only to the eligible patients of  
234 the agency or entity or must return the prescription drugs for  
235 or to the agency or entity. The contract provider or  
236 subcontractor must require proof from each person seeking to  
237 fill a prescription or obtain treatment that the person is an  
238 eligible patient of the agency or entity and must, at a minimum,  
239 maintain a copy of this proof as part of the records of the  
240 contractor or subcontractor required under sub-subparagraph d.

241 f. In addition to the departmental inspection authority set  
242 forth in s. 499.051, the establishment of the contract provider  
243 and subcontractor and all records pertaining to prescription  
244 drugs subject to this subparagraph shall be subject to  
245 inspection by the agency or entity. All records relating to  
246 prescription drugs of a manufacturer under this subparagraph  
247 shall be subject to audit by the manufacturer of those drugs,  
248 without identifying individual patient information.

249 (b) Any of the following activities, which is not a  
250 violation of s. 499.005(22) ~~s. 499.005(21)~~ if such activity is  
251 conducted in accordance with rules established by the  
252 department:

253 1. The distribution of a prescription drug among federal,  
254 state, or local government health care entities that are under  
255 common control and are authorized to purchase such prescription  
256 drug.

257 2. The distribution of a prescription drug or offer to  
258 distribute a prescription drug for emergency medical reasons,  
259 which may include transfers of prescription drugs by a retail  
260 pharmacy to another retail pharmacy to alleviate a temporary  
261 shortage. For purposes of this subparagraph, a drug shortage not

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caused by a public health emergency does not constitute an emergency medical reason.

3. The distribution of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider's license under chapter 401.

4. The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

5. The distribution of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

6. The distribution of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackaging prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that distributes prescription drugs pursuant to this subparagraph must reconcile all drugs distributed and returned and resolve any discrepancies in a

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timely manner.

Section 6. Paragraph (a) of subsection (10) of section 499.0051, Florida Statutes, is amended to read:

499.0051 Criminal acts.—

(10) VIOLATIONS OF S. 499.005 RELATED TO DEVICES AND COSMETICS; DISSEMINATION OF FALSE ADVERTISEMENT.—

(a) Any person who violates any of the provisions of s. 499.005 with respect to a device or cosmetic commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083 or as otherwise provided in this part, except that any person who violates s. 499.005(9) or (11) ~~s. 499.005(8) or (10)~~ with respect to a device or cosmetic commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part.

Section 7. This act shall take effect January 1, 2027.