

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

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

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

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

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

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

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

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88 499.01 Permits.—

89 (2) The following permits are established:

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

105 1. An exempt cosmetic manufacturer may only:

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

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

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

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

116 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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175 requirements of this subsection, or rules adopted by the
176 department to administer this subsection, is a violation of s.
177 499.005(15) ~~s. 499.005(14)~~, and a knowing failure is a violation
178 of s. 499.0051(3).

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

181 499.003 Definitions of terms used in this part.—As used in
182 this part, the term:

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

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

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

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

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

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

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

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

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

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

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

232 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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262 caused by a public health emergency does not constitute an
263 emergency medical reason.

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

269 4. The donation of a prescription drug by a health care
270 entity to a charitable organization that has been granted an
271 exemption under s. 501(c)(3) of the Internal Revenue Code of
272 1986, as amended, and that is authorized to possess prescription
273 drugs.

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

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

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291 timely manner.

292 Section 6. Paragraph (a) of subsection (10) of section
293 499.0051, Florida Statutes, is amended to read:

294 499.0051 Criminal acts.—

295 (10) VIOLATIONS OF S. 499.005 RELATED TO DEVICES AND
296 COSMETICS; DISSEMINATION OF FALSE ADVERTISEMENT.—297 (a) Any person who violates any of the provisions of s.
298 499.005 with respect to a device or cosmetic commits a
299 misdemeanor of the second degree, punishable as provided in s.
300 775.082 or s. 775.083; but, if the violation is committed after
301 a conviction of such person under this subsection has become
302 final, such person is guilty of a misdemeanor of the first
303 degree, punishable as provided in s. 775.082 or s. 775.083 or as
304 otherwise provided in this part, except that any person who
305 violates s. 499.005(9) or (11) ~~s. 499.005(8) or (10)~~ with
306 respect to a device or cosmetic commits a felony of the third
307 degree, punishable as provided in s. 775.082, s. 775.083, or s.
308 775.084, or as otherwise provided in this part.

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