HB 4005-A12 (LC 11) 2/16/18 (LHF/ps)

Requested by Representative BUEHLER

PROPOSED AMENDMENTS TO A-ENGROSSED HOUSE BILL 4005

1 On <u>page 1</u> of the printed A-engrossed bill, line 2, after "ORS" insert 2 "180.510,".

3 On page 5, after line 43, insert:

4 "SECTION 6. As used in this section and section 7 of this 2018 Act:

5 "(1) 'Drug' has the meaning given that term in ORS 689.005.

6 "(2) 'Essential off-patent or generic drug' means any prescription 7 drug or device used to deliver a prescription drug:

"(a) For which all exclusive marketing rights, if any, granted under
the Federal Food, Drug, and Cosmetic Act have expired;

"(b) That is actively manufactured and marketed for sale in the
 United States by three or fewer manufacturers;

12 "(c) That is made available for sale in this state; and

"(d)(A) That appears on the current Model List of Essential Medi cines adopted by the World Health Organization; or

15 "(B) That has been designated by the Health Evidence Review 16 Commission established in ORS 414.688 as an essential medicine due 17 to its efficacy in treating a life-threatening condition or a chronic 18 health condition that substantially impairs an individual's ability to 19 engage in activities of daily living.

"(3) 'Manufacture' has the meaning given that term in section 2 of
 this 2018 Act.

"(4) 'Manufacturer' has the meaning given that term in section 2
of this 2018 Act.

"(5) 'Prescription drug' has the meaning given that term in section
2 of this 2018 Act.

5 "(6)(a) 'Price gouging' means an unconscionable increase in the 6 price of a prescription drug by a manufacturer or wholesale distributor 7 of a prescription drug regardless of whether the manufacturer or 8 wholesale distributor sells a drug directly to a consumer.

9 "(b) 'Price gouging' does not include an unconscionable increase in 10 the price charged by a wholesale distributor of a prescription drug if 11 the increase is directly attributable to additional costs for the drug 12 imposed on the wholesale distributor by the manufacturer of the drug. 13 "(7) 'Unconscionable increase' means an increase in the price of a 14 prescription drug that:

"(a) Is excessive and not justified by the cost of producing the drug
 or the cost of appropriate expansion of access to the drug to promote
 public health; and

"(b) Results in consumers for whom the drug has been prescribed
 having no meaningful choice about whether to purchase the drug at
 an excessive price because of:

"(A) The importance of the drug to the health of the consumers;
 and

23 "(B) Insufficient competition in the market for the drug.

"<u>SECTION 7.</u> (1) A manufacturer or wholesale distributor of a pre scription drug may not engage in price gouging in the sale of an es sential off-patent or generic drug in this state.

"(2) Any person may file a complaint with the Attorney General
 asserting price gouging by a manufacturer or wholesale distributor of
 a prescription drug.

30 "(3) Upon receipt of the complaint, the Attorney General shall in-

1 vestigate the complaint and may:

2 "(a) Require the manufacturer of the drug to submit a statement:

3 "(A) Itemizing the components of the cost of producing the drug;

"(B) Identifying the circumstances and timing of any increase in
materials or manufacturing costs that cause an increase in the price
of the drug within the 12 months preceding the price increase;

"(C) Identifying the circumstances and timing of any expenditures
made by the manufacturer to expand access to the drug;

"(D) Describing any improvement in public health associated with
the expenditures identified in subparagraph (C) of this paragraph; and
"(E) Providing any other information that the manufacturer believes to be relevant as to whether the manufacturer has engaged in
price gouging.

"(b) Require a manufacturer or wholesale distributor of a prescription drug to produce any records or other documents that may
be relevant as to whether the manufacturer or wholesale distributor
has engaged in price gouging.

18 "(4) The Attorney General shall submit to the Health Evidence Re-19 view Commission established in ORS 414.688 all of the Attorney 20 General's investigative materials and any recommended findings. The 21 commission shall hold a public hearing and give the manufacturer or 22 wholesale distributor and any other persons adversely affected by the 23 price increase the opportunity to appear and provide testimony.

"(5) The commission shall determine whether a manufacturer or wholesale distributor of a prescription drug has engaged in price gouging. If the commission determines that a finding of price gouging is supported by the record, the Attorney General:

"(a) Shall impose a civil penalty, in the manner provided by ORS
 183.745, of at least \$10,000 but no more than an amount equal to 10
 percent of the manufacturer's or wholesale distributor's revenue from

1 the sales of the drug in this state.

"(b) May issue an order requiring the manufacturer or wholesale
distributor to reimburse any consumer, including a third party payer,
the portion of the price paid by the consumer that was found to be
excessive.

6 "(c) May issue an order requiring the manufacturer or wholesale 7 distributor to make the drug available for purchase in this state, for 8 up to 12 months from the date of the order, at the last price charged 9 by the manufacturer or wholesale distributor that was not found to 10 be excessive.

"(6) Orders described in subsection (5) of this 2018 Act are final or ders and may be appealed in the manner prescribed by ORS 183.480.

"(7) The Attorney General may remit or mitigate civil penalties or
 orders under subsection (5) of this section upon terms and conditions
 the Attorney General considers proper and consistent with the public
 health and safety.

"(8) Civil penalties collected under subsection (5) of this section
shall be paid over to the State Treasurer and deposited into the General Fund to be made available for general governmental expenses.

"(9) Any information provided to the Health Evidence Review
Commission by a manufacturer or wholesale distributor of prescription
drugs under subsection (4) of this section shall be considered a trade
secret under ORS 192.345.

²⁴ "<u>SECTION 8.</u> (1) If it appears to the Attorney General that a person ²⁵ has possession, custody or control of any information, document or ²⁶ other materials that are relevant to an investigation of a violation of ²⁷ section 7 of this 2018 Act, or that could lead to the discovery of rele-²⁸ vant information in an investigation of a violation of section 7 of this ²⁹ 2018 Act, the Attorney General may cause an investigative demand to ³⁰ be served upon the person. The investigative demand may require the 1 person:

"(a) To appear and testify under oath at the time and place stated
in the investigative demand;

4 "(b) To answer written interrogatories; or

"(c) To produce relevant documentary material or physical evidence
for examination at the time and place stated in the investigative demand.

"(2) An investigative demand under this section shall be served in
the manner provided by ORS 646.622 and may be enforced in the
manner provided by ORS 646.626.

"SECTION 9. (1) The Attorney General may bring a civil action in the name of the State of Oregon against a person who violates section 7 of this 2018 Act or for the purpose of seeking an injunction to restrain an actual or threatened violation of section 7 of this 2018 Act and compel compliance with section 7 of this 2018 Act.

"(2) In any action brought pursuant to this section, the state may
recover the costs of the investigation, the costs of the action, reasonable attorney fees and a civil penalty as provided in section 7 of this
2018 Act.

"(3) Unless expressly provided, the remedies or penalties under this
 section are cumulative to each other and to the remedies available
 under all other laws of the state.

²³ **"SECTION 10.** ORS 180.510 is amended to read:

²⁴ "180.510. The Department of Justice shall carry out the functions of the ²⁵ Attorney General under this section and ORS 20.098, 83.710 to 83.750, 83.820 ²⁶ to 83.895, 180.520, 336.184, 646.605 to 646.656, 646.990, 803.375, 803.385 and ²⁷ 815.410 to 815.430 **and section 7 of this 2018 Act**. The Attorney General may ²⁸ employ personnel necessary to carry out the duties and functions described ²⁹ in this section and fix their compensation, subject to any applicable pro-³⁰ visions of the State Personnel Relations Law.".

HB 4005-A12 2/16/18 Proposed Amendments to A-Eng. HB 4005

- 1 In line 44, delete "6" and insert "11".
- 2 On page 6, line 43, delete "7" and insert "12".
- 3 On page 8, line 12, delete "8" and insert "13".

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