II

116TH CONGRESS
1ST SESSION

S. 637

To prohibit price gouging in the sale of drugs.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 28, 2019

Mr. BLUMENTHAL (for himself, Mr. MERKLEY, Ms. HARRIS, Ms. KLOBUCHAR, Mr. SCHATZ, and Mr. SANDERS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To prohibit price gouging in the sale of drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Combatting Unreasonable Rises and Excessively High Drug Prices Act'' or the ''CURE High Drug Prices Act''.

SEC. 2. DEFINITIONS.

In this Act:

(1) AVERAGE MANUFACTURER PRICE.—The term ''average manufacturer price''—

(A) has the meaning given the term in section 1927(k) of the Social Security Act (42 U.S.C. 1396r–8(k)); or

(B) with respect to a drug for which there is no average manufacturer price as so defined, means the wholesale acquisition cost of the drug.

(2) DRUG.—The term ''drug''—

(A) has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); and

(B) includes biological products, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262).

(3) FEDERAL HEALTH CARE PROGRAM.—The term ''Federal health care program'' has the meaning given the term in section 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b(f)).

(4) MANUFACTURER.—The term ''manufacturer'' means a person—

(A) that holds the application for a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the license issued under section 351 of the Public Health Service Act (42 U.S.C. 262); or

(B) who is responsible for setting the price for the drug.

(5) PRICE GOUGING.—The term ''price gouging'' means an increase in the average manufacturer price of a qualifying drug that—

(A) is in substantial excess of an amount that could be reasonably justified by an increase in cost of producing the drug or by an increase in cost due to appropriate expansion of access to the drug to promote public health; and

(B) that because of insufficient competition in the marketplace, consumers cannot reasonably avoid.

(6) QUALIFYING DRUG.—The term ''qualifying drug'' means any drug, including a combination product whose primary mode of action is determined under section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) to be that of a drug, that—

(A) is subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and

(B) is covered by a Federal health care program.

(7) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 3. PRICE GOUGING PROHIBITED.

(a) IN GENERAL.—A manufacturer shall not engage in price gouging in the sale of a qualifying drug.

(b) PRESUMPTION.—Price gouging shall be presumed if the average manufacturer price has increased—

(1) 10 percent or more within the previous 12-month period;

(2) 20 percent or more in the previous 36-month period; or

(3) 30 percent or more within the previous 60-month period.

(c) NOTICE BY SECRETARY.—The Secretary shall notify the manufacturer of an increase, within the previous 2 years, in the average manufacturer price of a qualifying drug the Secretary has reason to believe constitutes price gouging, by sending notice to the manufacturer, requesting a statement of justification for the increase, which may include—

(1) itemizing the components of the cost of producing the qualifying drug;

(2) identifying the circumstances and timing of an increase in materials or manufacturing costs that caused an increase in the average manufacturer

price of the qualifying drug within the 5-year period preceding the date of the average manufacturer price increase;

(3) identifying the circumstances and timing of any expenditures made by the manufacturer to expand access to the qualifying drug and explaining any improvement in public health associated with those expenditures;

(4) providing sales and price information for other qualifying drugs with similar therapeutic effects, as relevant to assessing the extent of competition in the marketplace, and the choice available to consumers; and

(5) providing any other information that the manufacturer believes to be relevant to a determination of whether a violation of this Act has occurred.

(d) STATEMENT.—Not later than 45 days after the date on which a manufacturer receives a statement under subsection (c), the manufacturer shall submit to the Secretary a statement described in subsection (c).

(e) DETERMINATION BY SECRETARY.—If the Secretary determines, after review of the statement of justification, or based on reasonable belief if the manufacturer fails to submit a statement of justification as required, that the manufacturer has engaged in price

gouging with respect to a qualifying drug, the Secretary shall notify the manufacturer of the determination.

(f) REMEDY.—

(1) IN GENERAL.—The Secretary may order that a manufacturer determined under subsection (e) to have engaged in price gouging with respect to a qualifying drug—

(A) restore to any consumer, including a third-party payor, any excessive amount paid as a result of a price increase that violates this Act;

(B) make the drug available to participants of any qualified health plan or Federal health plan for a period of up to 1 year at the price at which the drug was made available to consumers immediately before the violation of this Act; or

(C) if the price gouging is done knowingly, or occurs after a previous determination by the Secretary or price gouging by the manufacturer, pay a civil penalty of up to 3 times the excessive amount the manufacturer received as a result of a violation of this Act.

(2) APPEALS.—Any person adversely affected by a determination of the Secretary under this sub-

section may obtain review of the determination in accordance with section 1128A(e) of the Social Security Act (42 U.S.C. 1320a–7a(e)).

(g) ENFORCEMENT BY ATTORNEY GENERAL.—

(1) IN GENERAL.—If a manufacturer determined under subsection (e) to have engaged in price gouging fails to comply with an order of the Secretary under subsection (f), the Secretary may refer the matter to the Attorney General for enforcement.

(2) SUBPOENAS.—The Attorney General may subpoena documents or testimony as may assist in establishing whether the manufacturer engaged in price gouging in violation of this Act.

(3) ACTION.—The Attorney General may bring an action in an appropriate district court for relief, including any relief described in subsection (f) and such further relief as the court determines is appropriate.

SEC. 4. EFFECTIVE DATE; APPLICABILITY.

This Act shall—

(1) take effect on January 1, 2020; and

(2) apply with respect to all increases in the average manufacturer price of a qualifying drug occurring on or after that date.

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