

116TH CONGRESS  
1ST SESSION

# H. R. 4158

To prohibit price gouging in the sale of drugs.

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IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 2019

Ms. PINGREE introduced the following bill; which was referred to the  
Committee on Energy and Commerce

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## A BILL

To prohibit price gouging in the sale of drugs.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Combatting Unreason-  
5 able Rises and Excessively High Drug Prices Act” or the  
6 “CURE High Drug Prices Act”.

7 **SEC. 2. DEFINITIONS.**

8 In this Act:

9 (1) **AVERAGE MANUFACTURER PRICE.**—The  
10 term “average manufacturer price”—

1 (A) has the meaning given the term in sec-  
2 tion 1927(k) of the Social Security Act (42  
3 U.S.C. 1396r–8(k)); or

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

8 (2) DRUG.—The term “drug”—

9 (A) has the meaning given the term in sec-  
10 tion 201 of the Federal Food, Drug, and Cos-  
11 metic Act (21 U.S.C. 321); and

12 (B) includes biological products, as defined  
13 in section 351 of the Public Health Service Act  
14 (42 U.S.C. 262).

15 (3) FEDERAL HEALTH CARE PROGRAM.—The  
16 term “Federal health care program” has the mean-  
17 ing given the term in section 1128B(f) of the Social  
18 Security Act (42 U.S.C. 1320a–7b(f)).

19 (4) MANUFACTURER.—The term “manufac-  
20 turer” means a person—

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

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

3 (5) PRICE GOUGING.—The term “price  
4 gouging” means an increase in the average manufac-  
5 turer price of a qualifying drug that—

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

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

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

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

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

1           (7) SECRETARY.—The term “Secretary” means  
2           the Secretary of Health and Human Services.

3 **SEC. 3. PRICE GOUGING PROHIBITED.**

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

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

8                 (1) 10 percent or more within the previous 12-  
9                 month period;

10                (2) 20 percent or more in the previous 36-  
11                month period; or

12                (3) 30 percent or more within the previous 60-  
13                month period.

14           (c) NOTICE BY SECRETARY.—The Secretary shall no-  
15           tify the manufacturer of an increase, within the previous  
16           2 years, in the average manufacturer price of a qualifying  
17           drug the Secretary has reason to believe constitutes price  
18           gouging, by sending notice to the manufacturer, request-  
19           ing a statement of justification for the increase, which  
20           may include—

21                (1) itemizing the components of the cost of pro-  
22                ducing the qualifying drug;

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

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

4 (3) identifying the circumstances and timing of  
5 any expenditures made by the manufacturer to ex-  
6 pand access to the qualifying drug and explaining  
7 any improvement in public health associated with  
8 those expenditures;

9 (4) providing sales and price information for  
10 other qualifying drugs with similar therapeutic ef-  
11 fects, as relevant to assessing the extent of competi-  
12 tion in the marketplace, and the choice available to  
13 consumers; and

14 (5) providing any other information that the  
15 manufacturer believes to be relevant to a determina-  
16 tion of whether a violation of this Act has occurred.

17 (d) STATEMENT.—Not later than 45 days after the  
18 date on which a manufacturer receives a statement under  
19 subsection (c), the manufacturer shall submit to the Sec-  
20 retary a statement described in subsection (c).

21 (e) DETERMINATION BY SECRETARY.—If the Sec-  
22 retary determines, after review of the statement of jus-  
23 tification, or based on reasonable belief if the manufac-  
24 turer fails to submit a statement of justification as re-  
25 quired, that the manufacturer has engaged in price

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

3 (f) REMEDY.—

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

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

12 (B) make the drug available to partici-  
13 pants of any qualified health plan or Federal  
14 health plan for a period of up to 1 year at the  
15 price at which the drug was made available to  
16 consumers immediately before the violation of  
17 this Act; or

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

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

1 section may obtain review of the determination in  
2 accordance with section 1128A(e) of the Social Secu-  
3 rity Act (42 U.S.C. 1320a–7a(e)).

4 (g) ENFORCEMENT BY ATTORNEY GENERAL.—

5 (1) IN GENERAL.—If a manufacturer deter-  
6 mined under subsection (e) to have engaged in price  
7 gouging fails to comply with an order of the Sec-  
8 retary under subsection (f), the Secretary may refer  
9 the matter to the Attorney General for enforcement.

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

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

19 **SEC. 4. EFFECTIVE DATE; APPLICABILITY.**

20 This Act shall—

21 (1) take effect on January 1, 2019; and

22 (2) apply with respect to all increases in the av-  
23 erage manufacturer price of a qualifying drug occur-  
24 ring on or after that date.

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