

116TH CONGRESS  
1ST SESSION

# S. 366

To shorten monopoly periods for prescription drugs that are the subjects of sudden price hikes.

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 6, 2019

Mr. DURBIN (for himself, Ms. HARRIS, Ms. SMITH, Ms. KLOBUCHAR, and Mr. BLUMENTHAL) 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 shorten monopoly periods for prescription drugs that are the subjects of sudden price hikes.

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 “Forcing Limits on  
5 Abusive and Tumultuous Prices” or the “FLAT Prices  
6 Act”.

7 **SEC. 2. REDUCED MARKET EXCLUSIVITY.**

8 (a) PENALTY.—If the manufacturer of a prescription  
9 drug approved under section 505 of the Federal Food,  
10 Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under

1 section 351 of the Public Health Service Act (42 U.S.C.  
2 262) increases the price of such drug as described in sub-  
3 section (b), any remaining period of market exclusivity  
4 with respect to such drug shall be reduced as follows:

5 (1) With respect to any price increase described  
6 in subsection (b), such market exclusivity shall be  
7 reduced by 180 days.

8 (2) For every 5 percent price increase over the  
9 10 percent, 18 percent, or 25 percent, respectively,  
10 threshold price increases described in subsection (b),  
11 such market exclusivity shall be reduced for an addi-  
12 tional 30 days.

13 (b) PRICE INCREASE.—A price increase described in  
14 this subsection is an increase in the wholesale acquisition  
15 cost (as defined in section 1847A(c)(6)(B) of the Social  
16 Security Act (42 U.S.C. 1395w–3a(c)(6)(B))) of a pre-  
17 scription drug of more than 10 percent over a 1-year pe-  
18 riod, more than 18 percent over a 2-year period, or more  
19 than 25 percent over a 3-year period.

20 (c) REPORT ON PRICE INCREASE.—

21 (1) IN GENERAL.—A drug manufacturer that  
22 increases the price of a prescription drug as de-  
23 scribed in subsection (b) shall report such increase  
24 to the Secretary of Health and Human Services (re-  
25 ferred to in this section as the “Secretary”) within

1 30 days of meeting the criteria for a price increase  
2 under such subsection.

3 (2) FAILURE TO SUBMIT REPORT.—In the case  
4 of a drug manufacturer that does not submit a re-  
5 port required under paragraph (1) within the 30-day  
6 period described in such paragraph, in addition to  
7 the penalty under subsection (a), the period of mar-  
8 ket exclusivity with respect to such drug shall be re-  
9 duced by 30 days for each day after the due date  
10 of the report until the report is submitted.

11 (d) WAIVER.—The Secretary may waive, or decrease,  
12 the reduction in the period of market exclusivity that  
13 would otherwise apply under subsection (a) with respect  
14 to a prescription drug if—

15 (1) the manufacturer of such drug submits—  
16 (A) a report under subsection (c)(1); and  
17 (B) an application for such a waiver, at  
18 such time, in such manner, and containing such  
19 information as the Secretary may require; and  
20 (2) based upon the information in such applica-  
21 tion, the Secretary determines that—

22 (A) the price increase is necessary to en-  
23 able production of the drug, does not unduly re-  
24 strict patient access to the drug , and does not  
25 negatively impact public health; and

1           (B) such waiver or decrease constitutes a  
2           deviation from the reduction in market exclu-  
3           sivity that would otherwise apply under sub-  
4           section (a) only to the extent necessary to  
5           achieve drug production objectives.

6           (e) PERIOD OF MARKET EXCLUSIVITY.—For pur-  
7           poses of this section, the term “period of market exclu-  
8           sivity” means any period of market exclusivity granted  
9           with respect to a prescription drug under clause (ii), (iii),  
10          or (iv) of section 505(c)(3)(E) of the Federal Food, Drug,  
11          and Cosmetic Act (21 U.S.C. 355(c)(3)(E)), section  
12          505(j)(5)(B)(iv) of such Act, clause (ii), (iii), or (iv) of  
13          section 505(j)(5)(F) of such Act, or paragraphs (6) or (7)  
14          of section 351(k) of the Public Health Service Act (42  
15          U.S.C. 262(k)).

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