

115TH CONGRESS  
2D SESSION

# H. R. 6576

To require drug manufacturers to disclose the prices of prescription drugs in any direct-to-consumer advertising and marketing to practitioners of a drug.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 26, 2018

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

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## A BILL

To require drug manufacturers to disclose the prices of prescription drugs in any direct-to-consumer advertising and marketing to practitioners of a drug.

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 “Drug-Price Trans-  
5 parency in Communications Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

1           (1) Direct-to-consumer advertising of prescrip-  
2           tion pharmaceuticals is legal in only 2 developed  
3           countries, the United States and New Zealand.

4           (2) Direct-to-consumer advertising of prescrip-  
5           tion pharmaceuticals is designed to cause patients to  
6           pressure physicians to prescribe certain medications.

7           (3) In 2015, pharmaceutical companies spent  
8           more than \$100,000,000 on advertising with respect  
9           to each of 16 brand-name drugs, primarily new and  
10          expensive drugs.

11          (4) Prescription rates of medications advertised  
12          directly to consumers have increased by 34.2 percent  
13          compared to a 5.1 percent increase in other pharma-  
14          ceuticals.

15          (5) Prescription pharmaceuticals cost more in  
16          the United States than they do in any other country.

17          (6) The American Medical Association has  
18          passed resolutions calling for the ban of direct-to-  
19          consumer advertising of prescription pharma-  
20          ceuticals, and to require price transparency in any  
21          direct-to-consumer advertising.

22          (7) The amount of spending by pharmaceutical  
23          companies in marketing to health care providers is  
24          more than 4 times the spending for direct-to-con-  
25          sumer advertising.

1 (8) Health care providers are more likely to  
2 prescribe a certain drug if they have received pay-  
3 ments or marketing materials from the manufac-  
4 turer of that drug.

5 **SEC. 3. PRICE DISCLOSURE REQUIREMENT FOR DIRECT-**  
6 **TO-CONSUMER DRUG ADVERTISEMENTS.**

7 (a) IN GENERAL.—Section 303(g)(1) of the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C. 333(g)(1)) is  
9 amended—

10 (1) by striking “(A)” and inserting “(i)”;

11 (2) by striking “(B)” and inserting (ii);

12 (3) by striking “(1) With respect” and inserting  
13 “(1)(A) With respect”;

14 (4) by striking “this paragraph” each place it  
15 appears and inserting “this subparagraph”;

16 (5) by striking “No other civil monetary pen-  
17 alties in this Act (including the civil penalty in sec-  
18 tion 303(f)(4))” and inserting “No civil monetary  
19 penalties (including the civil penalty in section  
20 303(f)(4)), other than the penalties under this sub-  
21 paragraph and subparagraph (B)”;

22 (6) by adding at the end the following:

23 “(B) With respect to a person who is a holder of an  
24 approved application under section 505 for a drug subject  
25 to section 503(b) or under section 351 of the Public

1 Health Service Act, any such person who disseminates or  
2 causes another party to disseminate a direct-to-consumer  
3 advertisement that does not include the wholesale acquisi-  
4 tion cost (as defined in section 1847A(c)(6)(B) of the So-  
5 cial Security Act) for a 30-day supply of the drug shall  
6 be liable to the United States for a civil penalty in an  
7 amount not to exceed \$1,000,000 for the first such viola-  
8 tion in any 3-year period, and not to exceed \$5,000,000  
9 for each subsequent violation in any 3-year period. For  
10 purposes of this subparagraph, all violations under this  
11 paragraph occurring in a single day shall be considered  
12 one violation. With respect to advertisements that appear  
13 in magazines or other publications that are published less  
14 frequently than daily, each issue date (whether weekly or  
15 monthly) shall be treated as a single day for the purpose  
16 of calculating the number of violations under this subpara-  
17 graph.”.

18 (b) TRANSFER OF FUNDS.—For each fiscal year,  
19 there are authorized to be appropriated, and are appro-  
20 priated, out of any funds not otherwise obligated, to the  
21 Director of the National Institutes of Health for purposes  
22 of carrying out medical research, an amount equal to the  
23 amount collected in penalties during the previous fiscal  
24 year for violations of section 303(g)(1)(B) of the Federal  
25 Food, Drug, and Cosmetic Act.

1 (c) REGULATIONS.—The Secretary of Health and  
2 Human Services, acting through the Commissioner of  
3 Food and Drugs, shall promulgate regulations to carry out  
4 subparagraph (B) of section 303(g)(1) of the Federal  
5 Food, Drug, and Cosmetic Act (21 U.S.C. 333(g)(1)), as  
6 added by subsection (a). Such regulations shall include  
7 provisions setting forth—

8 (1) a reasonable amount of time a manufac-  
9 turer has to update any direct-to-consumer adver-  
10 tising of a drug in accordance with such subpara-  
11 graph (B) after a change to the wholesale acquisi-  
12 tion cost of the drug; and

13 (2) the specific manner in which the wholesale  
14 acquisition cost of a drug is required to be conspicu-  
15 ously disclosed in such direct-to-consumer advertise-  
16 ments in order to communicate such single price  
17 metric to the public, which shall include visual and  
18 audio (as applicable) components of the advertise-  
19 ment, and which may include a brief qualitative ex-  
20 planation of reduced cost availability for certain con-  
21 sumers, such as through insurance cost-sharing ar-  
22 rangements or patient assistance programs.

1 **SEC. 4. DRUG MANUFACTURER DUTY TO DISCLOSE DRUG**  
2 **PRICES TO PRACTITIONERS.**

3 (a) DUTY TO DISCLOSE.—Whenever a drug manu-  
4 facturer, including any representative of the manufac-  
5 turer, communicates with a health care practitioner about  
6 a drug manufactured by the drug manufacturer, including  
7 through promotional, educational, or marketing commu-  
8 nications, meetings or paid events, and the provision of  
9 goods, gifts, and samples, the drug manufacturer shall dis-  
10 close to the practitioner the wholesale acquisition cost (as  
11 defined in section 1847A(c)(6)(B) of the Social Security  
12 Act (42 U.S.C. 1395w–3a(c)(6)(B))) for a 30-day supply  
13 of the drug, which may include a brief qualitative expla-  
14 nation of reduced cost availability for certain consumers  
15 that is consistent with the regulations described in section  
16 3(c)(2).

17 (b) ENFORCEMENT BY FEDERAL TRADE COMMIS-  
18 SION.—

19 (1) UNFAIR OR DECEPTIVE ACTS OR PRAC-  
20 TICES.—A violation of subsection (a) by a person  
21 with respect to whom the Commission is empowered  
22 under section 5(a)(2) of the Federal Trade Commis-  
23 sion Act (15 U.S.C. 45(a)(2)) shall be treated as a  
24 violation of a rule defining an unfair or deceptive act  
25 or practice prescribed under section 18(a)(1)(B) of

1 the Federal Trade Commission Act (15 U.S.C.  
2 57a(a)(1)(B)).

3 (2) POWERS OF FEDERAL TRADE COMMIS-  
4 SION.—

5 (A) IN GENERAL.—The Federal Trade  
6 Commission shall enforce this section in the  
7 same manner, by the same means, and with the  
8 same jurisdiction, powers, and duties as though  
9 all applicable terms and provisions of the Fed-  
10 eral Trade Commission Act (15 U.S.C. 41 et  
11 seq.) were incorporated into and made a part of  
12 this Act.

13 (B) PRIVILEGES AND IMMUNITIES.—Any  
14 person who violates this section shall be subject  
15 to the penalties and entitled to the privileges  
16 and immunities provided in the Federal Trade  
17 Commission Act (15 U.S.C. 41 et seq.).

18 (c) RULEMAKING.—The Federal Trade Commission  
19 shall promulgate in accordance with section 553 of title  
20 5, United States Code, such rules as may be necessary  
21 to carry out this section.

22 (d) SAVINGS PROVISION.—Nothing in this section  
23 shall be construed to limit, impair, or supersede the oper-

- 1 ation of the Federal Trade Commission Act or any other
- 2 provision of Federal law.

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