

115TH CONGRESS 1ST SESSION

S. 2157

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

IN THE SENATE OF THE UNITED STATES

NOVEMBER 16, 2017

Mr. Durbin (for himself, Mr. King, Mr. Brown, Mr. Franken, Ms. Hassan, and Ms. Harris) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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.
 - (2) Direct-to-consumer advertising of prescription pharmaceuticals is designed to cause patients to pressure physicians to prescribe certain medications.
 - (3) In 2015, pharmaceutical companies spent more than \$100,000,000 on advertising with respect to each of 16 brand-name drugs, primarily new and expensive drugs.
 - (4) Prescription rates of medications advertised directly to consumers have increased by 34.2 percent compared to a 5.1 percent increase in other pharmaceuticals.
 - (5) Prescription pharmaceuticals cost more in the United States than they do in any other country.
 - (6) The American Medical Association has passed resolutions calling for the ban of direct-to-consumer advertising of prescription pharmaceuticals, and to require price transparency in any direct-to-consumer advertising.
 - (7) The amount of spending by pharmaceutical companies in marketing to health care providers is more than 4 times the spending for direct-to-consumer 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)"; and
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-
- tising of a drug in accordance with such subpara-
- graph (B) after a change to the wholesale acquisi-
- tion cost of the drug; and
- 13 (2) the specific manner in which the wholesale
- acquisition cost of a drug is required to be conspicu-
- ously disclosed in such direct-to-consumer advertise-
- ments in order to communicate such single price
- metric to the public, which shall include visual and
- audio (as applicable) components of the advertise-
- ment, and which may include a brief qualitative ex-
- 20 planation of reduced cost availability for certain con-
- sumers, such as through insurance cost-sharing ar-
- rangements or patient assistance programs.

SEC. 4. DRUG MANUFACTURER DUTY TO DISCLOSE DRUG

2.	PRICES TO PRACTITIONERS.
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- 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(e)(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-
- sion Act (15 U.S.C. 45(a)(2)) shall be treated as a
- violation of a rule defining an unfair or deceptive act
- or practice prescribed under section 18(a)(1)(B) of

- the Federal Trade Commission Act (15 U.S.C.
 57a(a)(1)(B)).
- 3 (2) Powers of Federal trade commis-4 sion.—
 - (A) IN GENERAL.—The Federal Trade Commission shall enforce this section in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of 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-

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

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