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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.

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.

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 ''Drug-Price Transparency in Communications Act''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Direct-to-consumer advertising of prescription pharmaceuticals is legal in only 2 developed 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.

(8) Health care providers are more likely to prescribe a certain drug if they have received payments or marketing materials from the manufacturer of that drug.

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

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

(1) by striking ''(A)'' and inserting ''(i)'';

(2) by striking ''(B)'' and inserting (ii);

(3) by striking ''(1) With respect'' and inserting ''(1)(A) With respect'';

(4) by striking ''this paragraph'' each place it appears and inserting ''this subparagraph'';

(5) by striking ''No other civil monetary penalties in this Act (including the civil penalty in section 303(f)(4))'' and inserting ''No civil monetary penalties (including the civil penalty in section 303(f)(4)), other than the penalties under this subparagraph and subparagraph (B)''; and

(6) by adding at the end the following:

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

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

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

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

(1) a reasonable amount of time a manufacturer has to update any direct-to-consumer advertising of a drug in accordance with such subparagraph (B) after a change to the wholesale acquisition cost of the drug; and

(2) the specific manner in which the wholesale acquisition cost of a drug is required to be conspicuously disclosed in such direct-to-consumer advertisements in order to communicate such single price metric to the public, which shall include visual and audio (as applicable) components of the advertisement, and which may include a brief qualitative explanation of reduced cost availability for certain consumers, such as through insurance cost-sharing arrangements or patient assistance programs.

SEC. 4. DRUG MANUFACTURER DUTY TO DISCLOSE DRUG PRICES TO PRACTITIONERS.

(a) DUTY TO DISCLOSE.—Whenever a drug manufacturer, including any representative of the manufacturer, communicates with a health care practitioner about a drug manufactured by the drug manufacturer, including through promotional, educational, or marketing communications, meetings or paid events, and the provision of goods, gifts, and samples, the drug manufacturer shall disclose to the practitioner the wholesale acquisition cost (as defined in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B))) for a 30-day supply of the drug, which may include a brief qualitative explanation of reduced cost availability for certain consumers that is consistent with the regulations described in section 3(c)(2).

(b) ENFORCEMENT BY FEDERAL TRADE COMMISSION.—

(1) UNFAIR OR DECEPTIVE ACTS OR PRACTICES.—A violation of subsection (a) by a person with respect to whom the Commission is empowered under section 5(a)(2) of the Federal Trade Commission 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)).

(2) POWERS OF FEDERAL TRADE COMMISSION.—

(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.

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

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

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

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

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