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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend title XI of the Social Security Act to require that direct-to-consumer advertisements for drugs and biologicals include an appropriate disclosure of pricing information.

IN THE HOUSE OF REPRESENTATIVES

Ms. SPANBERGER introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title XI of the Social Security Act to require that direct-to-consumer advertisements for drugs and biologicals include an appropriate disclosure of pricing information.

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 for Consumers Act of 2023'' or the ''DTC Act of 2023''.

SEC. 2. FINDINGS; SENSE OF CONGRESS.

(a) FINDINGS.—Congress finds the following:

(1) Direct-to-consumer advertising of prescription pharmaceuticals is legally permitted in only 2 developed countries, the United States and New Zealand.

(2) In 2018, pharmaceutical ad spending exceeded $6,046,000,000, a 4.8-percent increase over 2017, resulting in the average American seeing 9 drug advertisements per day.

(3) The most commonly advertised medication in the United States in 2020 had a list price of more than $6,000 for a one-month's supply.

(4) A 2021 Government Accountability Office report found that two-thirds of all direct-to-consumer drug advertising between 2016 and 2018 was concentrated among 39 brand-name drugs or biologicals, about half of which were recently approved by the Food and Drug Administration.

(5) According to a 2011 Congressional Budget Office report, pharmaceutical manufacturers advertise their products directly to consumers in an attempt to boost demand for their products and thereby raise the price that consumers are willing to pay, increase the quantity of drugs sold, or achieve some combination of the two.

(6) Studies, including a 2012 systematic review published in the Annual Review of Public Health, a 2005 randomized trial published in the Journal of the American Medical Association, and a 2004 survey published in Health Affairs, show that patients are more likely to ask their doctor for a specific medication and for the doctor to write a prescription for it, if a patient has seen an advertisement for such medication, even if such medication is not the most clinically appropriate for the patient or if a lower cost generic medication may be available.

(7) According to a 2011 Congressional Budget Office report, the average number of prescriptions written for newly approved brand-name drugs with direct-to-consumer advertising was 9 times greater than the average number of prescriptions written for newly approved brand-name drugs without direct-to-consumer advertising.

(8) The Centers for Medicare & Medicaid Services is the single largest drug payer in the United States. Between 2016 and 2018, 58 percent of the $560,000,000,000 in Medicare drug spending was for advertised drugs, and in 2018 alone, the 20 most advertised drugs on television cost Medicare and Medicaid a combined $34,000,000,000.

(9) A 2021 Government Accountability Office report found that direct-to-consumer advertising may have contributed to increases in Medicare beneficiary use and spending among certain drugs.

(10) The American Medical Association has passed resolutions supporting the requirement for price transparency in any direct-to-consumer advertising, stating that such advertisements on their own ''inflate demand for new and more expensive drugs, even when these drugs may not be appropriate''.

(11) A 2019 study published in the Journal of the American Medical Association found that health care consumers dramatically underestimate their out-of-pocket costs for certain expensive medications, but once they learn the wholesale acquisition cost (in this section referred to as the ''WAC'') of the product, they are far better able to approximate their out-of-pocket costs.

(12) Approximately half of Americans have high-deductible health plans, under which they often pay the list price of a drug until their insurance deductible is met. All of the top Medicare prescription drug plans use coinsurance rather than fixed-dollar copayments for medications on nonpreferred drug tiers, exposing beneficiaries to WAC prices.

(13) Section 119 of division CC of the Consolidated Appropriations Act, 2021 (Public Law 116–260) requires the Secretary of Health and Human Services to increase the use of real-time benefit tools to lower beneficiary costs. However, there still remains a lack of available pricing tools so patients may not learn of their medication's cost until after being given a prescription for the medication. A 2013 study published in The Oncologist found that one-quarter of all cancer patients chose not to fill a prescription due to cost.

(14) The Federal Government already exercises its authority to oversee certain aspects of direct-to-consumer drug advertising, including required disclosures of information related to side effects, contraindications, and effectiveness.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) a lack of transparency in pricing for pharmaceuticals has led to a lack of competition for such pharmaceuticals, as evidenced by a finding by the Department of Health and Human Services that ''Consumers of pharmaceuticals are currently missing information that consumers of other products can more readily access, namely the list price of the

product, which acts as a point of comparison when judging the reasonableness of prices offered for potential substitute products'' (84 Fed. Reg. 20735);

(2) in an age where price information is ubiquitous, the prices of pharmaceuticals remain shrouded in secrecy and limited to those who subscribe to expensive drug price reporting services, which typically include pharmaceutical manufacturers or other health care industry entities and not the general public;

(3) greater insight and transparency into drug prices will help consumers know if they can afford to complete a course of therapy before deciding to initiate that course of therapy;

(4) price shopping is the mark of rational economic behavior, and markets operate more efficiently when consumers have relevant information about a product, including its price, before making an informed decision about whether to buy that product;

(5) providing consumers with basic price information may result in the selection of lesser cost alternatives, all else being equal relative to the patient's care, and is integral to providing adequate competition in the market;

(6) the WAC is a factual, objective, and uncontroversial definition for the list price of a medication, in that it is defined in statute, reflects an understood place in the supply chain, and is at the sole discretion of the manufacturer to set;

(7) there is a governmental interest in ensuring that consumers who seek to purchase pharmaceuticals for purposes of promoting their health and safety understand the objective list price of any pharmaceutical that they are encouraged through advertisements to purchase, which allows consumers to make informed purchasing decisions; and

(8) there is a governmental interest in mitigating wasteful expenditures and promoting the efficient administration of the Medicare program by slowing the growth of Federal spending on prescription drugs.

SEC. 3. REQUIREMENT THAT DIRECT-TO-CONSUMER ADVERTISEMENTS FOR DRUGS AND BIOLOGICALS INCLUDE AN APPROPRIATE DISCLOSURE OF PRICING INFORMATION.

Part A of title XI of the Social Security Act is amended by adding at the end the following new section:

"SEC. 1150D. REQUIREMENT THAT DIRECT-TO-CONSUMER ADVERTISEMENTS FOR DRUGS AND BIOLOGICALS INCLUDE AN APPROPRIATE DISCLOSURE OF PRICING INFORMATION.

"(a) REQUIREMENT.—

"(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall require that each direct-to-consumer advertisement for a drug or biological for which payment is available under title XVIII or XIX and which is required to include the information relating to side effects, contraindications, and effectiveness described in section 202.1(e)(1) of title 21, Code of Federal Regulations (or any successor regulation) also include an appropriate disclosure of pricing information, as described in subsection (b), with respect to such drug or biological.

"(2) EXEMPTION.—The requirement under paragraph (1) shall not apply to a drug or biological for which the wholesale acquisition cost for a 30-day supply of (or, if applicable, a typical course of treatment for) such drug or biological is less than $35.

"(b) APPROPRIATE DISCLOSURE OF PRICING INFORMATION.—For the purposes of subsection (a), an appropriate disclosure of pricing information, with respect to a drug or biological, shall—

''(1) disclose the wholesale acquisition cost for a 30-day supply of (or, if applicable, a typical course of treatment for) such drug or biological; and

''(2) be presented clearly and conspicuously.

''(c) RULEMAKING.—Not later than 1 year after the date of enactment of this section, the Secretary, acting through the Administrator of the Centers for Medicare and Medicaid Services, shall promulgate final regulations to carry out this section, including—

''(1) the visual and audio components required to communicate the wholesale acquisition cost in the appropriate manner for the medium of the advertisement;

''(2) the reasonable amount of time a manufacturer has to update any direct-to-consumer advertisement to reflect any change to the wholesale acquisition cost of the advertised drug or biological; and

''(3) the way in which a manufacturer may include a brief statement explaining that certain consumers may pay a different amount depending on their insurance coverage.

''(d) SANCTIONS.—Any manufacturer of a drug or biological, or an agent of such manufacturer, that violates the requirement of this section may be subject to a civil

money penalty of not more than $100,000 for each such violation. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under the preceding sentence in the same manner as they apply to a penalty or proceeding under section 1128A(a).

''(e) PUBLIC REPORTING SYSTEM.—In order to enforce the requirement under this section, the Secretary may establish a public reporting system—

''(1) to build awareness of such requirement; and

''(2) allow for reporting of manufacturers that fail to comply with such requirement.

''(f) DEFINITIONS.—In this section:

''(1) DRUG AND BIOLOGICAL.—The terms 'drug' and 'biological' have the meaning given such terms in section 1861(t).

''(2) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B).

''(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for the purposes of carrying out this section.''.