

117TH CONGRESS
1ST SESSION

S. 2304

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

IN THE SENATE OF THE UNITED STATES

JUNE 24, 2021

Mr. DURBIN (for himself, Mr. GRASSLEY, and Mr. KING) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

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

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 for Competition Act of 2021” or the “DTC Act
6 of 2021”.

7 **SEC. 2. FINDINGS; SENSE OF THE SENATE.**

8 (a) FINDINGS.—Congress finds the following:

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

5 (2) In 2018, pharmaceutical ad spending ex-
6 ceeded \$6,046,000,000, a 4.8 percent increase over
7 2017, resulting in the average American seeing 9
8 drug advertisements per day.

9 (3) The most commonly advertised medication
10 in the United States has a list price of more than
11 \$6,000 for a one-month's supply.

12 (4) A 2021 Government Accountability Office
13 report found that two-thirds of all direct-to-con-
14 sumer drug advertising between 2016 and 2018 was
15 concentrated among 39 brand-name drugs or biologi-
16 cal products, about half of which were recently ap-
17 proved by the Food and Drug Administration.

18 (5) According to a 2011 Congressional Budget
19 Office report, pharmaceutical manufacturers adver-
20 tise their products directly to consumers in an at-
21 tempt to boost demand for their products and there-
22 by raise the price that consumers are willing to pay,
23 increase the quantity of drugs sold, or achieve some
24 combination of the two.

1 (6) Studies, including a 2012 systematic review
2 published in the Annual Review of Public Health, a
3 2005 randomized trial published in the Journal of
4 the American Medical Association, and a 2004 sur-
5 vey published in Health Affairs, show that patients
6 are more likely to ask their doctor for a specific
7 medication and for the doctor to write a prescription
8 for it, if a patient has seen an advertisement for
9 such medication, even if such medication is not the
10 most clinically appropriate for the patient or if a
11 lower-cost generic medication may be available.

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

19 (8) The Centers for Medicare & Medicaid Serv-
20 ices is the single largest drug payer in the United
21 States. Between 2016 and 2018, 58 percent of the
22 \$560,000,000,000 in Medicare drug spending was
23 for advertised drugs, and in 2018 alone, the 20 most
24 advertised drugs on television cost Medicare and
25 Medicaid a combined \$34,000,000,000.

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

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

11 (11) A 2019 study published in the Journal of
12 the American Medical Association found that health
13 care consumers dramatically underestimate their
14 out-of-pocket costs for certain expensive medications,
15 but once they learn the wholesale acquisition cost (in
16 this section referred to as the “WAC”) of the prod-
17 uct, they are far better able to approximate their
18 out-of-pocket costs.

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

1 (13) Section 119 of division CC of the Consoli-
2 dated Appropriations Act, 2021 (Public Law 116–
3 260) requires the Secretary of Health and Human
4 Services to increase the use of real-time benefit tools
5 to lower beneficiary costs. However, there still re-
6 mains a lack of available pricing tools so patients
7 may not learn of their medication’s cost until after
8 being given a prescription for the medication. A
9 2013 study published in *The Oncologist* found that
10 one-quarter of all cancer patients chose not to fill a
11 prescription due to cost.

12 (14) The Federal Government already exercises
13 its authority to oversee certain aspects of direct-to-
14 consumer drug advertising, including required disclo-
15 sures of information related to side effects, contra-
16 indications, and effectiveness.

17 (b) SENSE OF CONGRESS.—It is the sense of Con-
18 gress that—

19 (1) a lack of transparency in pricing for phar-
20 maceuticals has led to a lack of competition for such
21 pharmaceuticals, as evidenced by a finding by the
22 Department of Health and Human Services that
23 “Consumers of pharmaceuticals are currently miss-
24 ing information that consumers of other products
25 can more readily access, namely the list price of the

1 product, which acts as a point of comparison when
2 judging the reasonableness of prices offered for po-
3 tential substitute products” (84 Fed. Reg. 20735);

4 (2) in an age where price information is ubiq-
5 uitous, the prices of pharmaceuticals remain shroud-
6 ed in secrecy and limited to those who subscribe to
7 expensive drug price reporting services, which typi-
8 cally include pharmaceutical manufacturers or other
9 health care industry entities and not the general
10 public;

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

15 (4) price shopping is the mark of rational eco-
16 nomic behavior, and markets operate more efficiently
17 when consumers have relevant information about a
18 product, including its price, before making an in-
19 formed decision about whether to buy that product;

20 (5) providing consumers with basic price infor-
21 mation may result in the selection of lesser cost al-
22 ternatives, all else being equal relative to the pa-
23 tient’s care, and is integral to providing adequate
24 competition in the market;

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

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

13 (8) there is a governmental interest in miti-
 14 gating wasteful expenditures and promoting the effi-
 15 cient administration of the Medicare program by
 16 slowing the growth of Federal spending on prescrip-
 17 tion drugs.

18 **SEC. 3. REQUIREMENT THAT DIRECT-TO-CONSUMER AD-**
 19 **VERTISEMENTS FOR PRESCRIPTION DRUGS**
 20 **AND BIOLOGICAL PRODUCTS INCLUDE AN**
 21 **APPROPRIATE DISCLOSURE OF PRICING IN-**
 22 **FORMATION.**

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

1 **“SEC. 1150D. REQUIREMENT THAT DIRECT-TO-CONSUMER**
 2 **ADVERTISEMENTS FOR PRESCRIPTION**
 3 **DRUGS AND BIOLOGICAL PRODUCTS IN-**
 4 **CLUDE AN APPROPRIATE DISCLOSURE OF**
 5 **PRICING INFORMATION.**

6 “(a) IN GENERAL.—The Secretary shall require that
 7 each direct-to-consumer advertisement for a prescription
 8 drug or biological product for which payment is available
 9 under title XVIII or XIX includes an appropriate disclo-
 10 sure of pricing information with respect to the drug or
 11 product.

12 “(b) APPROPRIATE DISCLOSURE OF PRICING INFOR-
 13 MATION.—For the purposes of subsection (a), an appro-
 14 priate disclosure of pricing information, with respect to
 15 a prescription drug or biological product—

16 “(1) shall include a disclosure of the wholesale
 17 acquisition cost (as defined in section
 18 1847A(c)(6)(B)) for a 30-day supply of (or, if appli-
 19 cable, a typical course of treatment for) such drug
 20 or product;

21 “(2) shall be presented clearly and conspicu-
 22 ously, as appropriate for the medium of the adver-
 23 tisement; and

24 “(3) may include additional qualitative or quan-
 25 titative information regarding the price of such drug
 26 or product explaining that certain patients may pay

1 a different amount depending on their insurance
2 coverage.

3 “(c) ENFORCEMENT.—Any person who violates the
4 requirement of this section may be subject to a civil money
5 penalty of not more than \$100,000 for each such violation
6 or to another enforcement mechanism determined by the
7 Secretary. Any civil money penalty shall be imposed and
8 collected in the same manner as civil money penalties
9 under subsection (a) of section 1128A are imposed and
10 collected under that section.

11 “(d) REGULATIONS.—The Secretary, acting through
12 the Administrator of the Centers for Medicare & Medicaid
13 Services, shall promulgate regulations to carry out this
14 section. Such regulations shall determine the components
15 of the requirement under this section, including the forms
16 of advertising, the manner of disclosure, the appropriate
17 sanctions, and the appropriate disclosure of pricing infor-
18 mation.”.

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