119TH CONGRESS	$\mathbf{C}$	
1st Session	<b>5.</b>	

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

## IN THE SENATE OF THE UNITED STATES

Mr. Durbin (for himself, Mr. Grassley, Mr. King, Ms. Ernst, Ms. Smith, Mr. Welch, Mr. Blumenthal, and Ms. Baldwin) introduced the following bill; which was read twice and referred to the Committee on

## 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 Consumers Act of 2025" or the "DTC Act
- 6 of 2025".

## SEC. 2. FINDINGS; SENSE OF THE SENATE.

- 2 (a) FINDINGS.—Congress finds the following:
- (1) Direct-to-consumer advertising of prescrip tion pharmaceuticals is legally permitted in only 2
  developed countries, the United States and New
- 6 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 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.

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(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 the doctor is more likely 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.

4 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 this section referred to as the "WAC") of the prod-16 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

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.

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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 potential substitute products" (84 Fed. Reg. 20735); 3 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

competition in the market;

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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 sections

1	"SEC. 1150D. REQUIREMENT THAT DIRECT-TO-CONSUMER
2	ADVERTISEMENTS FOR PRESCRIPTION
3	DRUGS AND BIOLOGICALS INCLUDE AN AP-
4	PROPRIATE DISCLOSURE OF PRICING INFOR-
5	MATION.
6	"(a) Requirement.—
7	"(1) In General.—Subject to paragraph (2),
8	not later than July 1, 2026, the Secretary shall re-
9	quire that each direct-to-consumer advertisement for
10	a prescription drug or biological product for which
11	payment is available under title XVIII or XIX and
12	that is required to include the information relating
13	to side effects, contraindications, and effectiveness
14	described in section 202.1(e)(1) of title 21, Code of
15	Federal Regulations (or any successor regulation)
16	also include an appropriate disclosure of pricing in-
17	formation, as described in subsection (b), with re-
18	spect to such prescription drug or biological product.
19	"(2) Exemption.—The requirement under
20	paragraph (1) shall not apply to a prescription drug
21	or biological product for which the wholesale acquisi-
22	tion cost for a 30-day supply of (or, if applicable, a
23	typical course of treatment as set forth in the ap-
24	proved label for the primary indication addressed in
25	the advertisement for) such prescription drug or bio-
26	logical product is less than \$35.

1	"(b) Appropriate Disclosure of Pricing Infor-
2	MATION.—For the purposes of subsection (a), an appro-
3	priate disclosure of pricing information, with respect to
4	a prescription drug or biological product—
5	"(1) shall clearly and conspicuously disclose the
6	wholesale acquisition cost for a 30-day supply of (or
7	if applicable, a typical course of treatment for) such
8	prescription drug or biological product; and
9	"(2) may explain that a consumer may pay a
10	different amount for such prescription drug or bio-
11	logical product than such wholesale acquisition cost
12	depending on the health insurance coverage of the
13	consumer.
14	"(c) Rulemaking.—Not later than 1 year after the
15	date of enactment of this section, the Secretary shall pro-
16	mulgate final regulations to carry out this section, includ-
17	ing establishing requirements for—
18	"(1) the visual and audio components, with re-
19	spect to each medium of direct-to-consumer adver-
20	tisement, to communicate the wholesale acquisition
21	cost of the advertised prescription drug or biological
22	product; and
23	"(2) the amount of time for a manufacturer to
24	update any direct-to-consumer advertisement to re-
25	flect any change to the wholesale acquisition cost of

1 the advertised prescription drug or biological prod-

- 2 uct.
- 3 "(d) Sanctions.—Any manufacturer of a prescrip-
- 4 tion drug or biological product, or an agent of such manu-
- 5 facturer, that violates the requirement of this section may
- 6 be subject to a civil money penalty of not more than
- 7 \$100,000 for each such violation. The provisions of section
- 8 1128A (other than subsections (a) and (b)) shall apply
- 9 to civil money penalties under the preceding sentence in
- 10 the same manner as they apply to a penalty or proceeding
- 11 under section 1128A(a).
- 12 "(e) Public Reporting.—In order to enforce the
- 13 requirement under this section, the Secretary may use in-
- 14 formation reported about manufacturers that fail to com-
- 15 ply with such requirement.
- 16 "(f) Definitions.—In this section:
- 17 "(1) BIOLOGICAL PRODUCT.—The term 'bio-
- logical product' means any biological product (as de-
- fined in section 351(i) of the Public Health Service
- Act) that is licensed by the Food and Drug Adminis-
- 21 tration pursuant to section 351 and is subject to the
- requirements of section 503(b)(1) of the Federal
- Food, Drug, and Cosmetic Act.
- 24 "(2) Prescription drug.—The term 'pre-
- 25 scription drug' means any drug (as defined in sec-

1	tion 201(g) of the Federal Food, Drug, and Cos-
2	metic Act) that has been approved by the Food and
3	Drug Administration pursuant to section 505 of
4	such Act and is subject to the requirements of sec-
5	tion 503(b)(1) of such Act.
6	"(3) Wholesale acquisition cost.—The
7	term 'wholesale acquisition cost' has the meaning
8	given such term in section 1847A(c)(6)(B).
9	"(g) Authorization of Appropriations.—There
10	are authorized to be appropriated such sums as may be

11 necessary for the purposes of carrying out this section.".