

119TH CONGRESS
1ST SESSION

S. 652

To provide for the regulation of certain communications regarding prescription drugs.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 20, 2025

Mr. DURBIN (for himself and Mr. MARSHALL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for the regulation of certain communications regarding prescription drugs.

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 “Protecting Patients
5 from Deceptive Drug Ads Act”.

6 **SEC. 2. REGULATION OF CERTAIN COMMUNICATIONS RE-**
7 **GARDING PRESCRIPTION DRUGS.**

8 (a) REGULATION OF COMMUNICATIONS.—

1 (1) IN GENERAL.—Section 303 of the Federal
 2 Food, Drug, and Cosmetic Act (21 U.S.C. 333) is
 3 amended by adding at the end the following:

4 “(h)(1) In the case of a social media influencer or
 5 health care provider who makes false or misleading com-
 6 munications regarding a drug approved under section 505
 7 or licensed under section 351 of the Public Health Service
 8 Act, and subject to section 503(b), or compounded in ac-
 9 cordance with section 503A or 503B, shall be liable to the
 10 United States for a civil penalty in an amount described
 11 in paragraph (g)(1), in accordance with a process similar
 12 to the process described in paragraph (g)(2).

13 “(2) For purposes of this paragraph—

14 “(A) the term ‘false or misleading communica-
 15 tions’—

16 “(i) means advertisements or promotional
 17 communications on a social media platform
 18 from which there is a financial benefit to the
 19 person engaging in such communications re-
 20 garding such drug—

21 “(I)(aa) that are made knowingly or
 22 recklessly; and

23 “(bb) contain a false or inaccurate
 24 statement or material omission of fact re-

1 garding a drug described in subparagraph
2 (1); or

3 “(II) fail to include information in
4 brief summary relating to side effects, con-
5 traindications, and effectiveness of the
6 drug in the same manner and to the same
7 extent as such information is required in
8 prescription drug advertisements pursuant
9 to section 502(n); and

10 “(ii) does not include—

11 “(I) statements that take place in the
12 course of bona fide patient care or medical
13 research that are made by professionals
14 engaged in such patient care or medical re-
15 search; or

16 “(II) statements that describe the per-
17 son’s own experience, opinion, or value
18 judgment; and

19 “(B) the term ‘social media influencer’ means a
20 private individual who has perceived credibility or
21 popularity and who expresses their opinions, beliefs,
22 findings, recommendations, or experience on social
23 media platforms to an audience, including in a man-
24 ner conveying trust or expertise on a topic, for the
25 purpose to promoting or advertising certain informa-

tion or products or inducing behavior by the audience.”.

(2) GUIDANCE.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall issue guidance on how the Secretary will administer paragraph (h) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as added by paragraph (1), including with respect to the factors that will be considered in determining whether a communication is false or misleading communication, as defined in such paragraph (h), including—

(A) the various types of statements or omission of facts regarding a prescription drug that would constitute false or misleading, such as statements or omissions related to safety, efficacy, approved or unapproved uses, directions for use from the label approved by the Food and Drug Administration, scientific information, or other similar attributes;

(B) whether the inclusion of the information in brief summary described in paragraph (h)(2)(A)(i)(III) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

333), as added by paragraph (1), alone is sufficient in each circumstance to avoid such a determination;

(C) actions taken by the social media influencer, health care provider, or other person to demonstrate compliance with such paragraph (h); and

(D) characteristics specific to various social media platforms, and the speed of dissemination of the content on such platform.

(3) ADDITIONAL REQUIREMENTS FOR TELE-
HEALTH PROVIDERS.—

(A) IN GENERAL.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by adding at the end the following: “For purposes of this paragraph, ‘manufacturer, packer, or distributor’ includes a person who issues or causes to be issued an advertisement or other descriptive printed matter with respect to a specific drug subject to section 503(b)(1) or compounded in accordance with section 503A or 503B, and who directly or indirectly offers to bring together a potential patient and a prescriber or dispenser through use of electronic information

1 and telecommunication technologies to engage
2 in prescribing or dispensing of any drug subject
3 to section 503(b)(1). Nothing in this paragraph
4 shall apply to a private communication between
5 a practitioner licensed by law to prescribe or
6 dispense a prescription drug (or an individual
7 under the direct supervision of such a practi-
8 tioner) and an individual patient or their rep-
9 resentative.”.

10 (B) REGULATIONS.—Not later than 1 year
11 after the date of enactment of this Act, the Sec-
12 retary shall update the regulations promulgated
13 to carry out section 502(n) of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C.
15 352(n)) in accordance with the amendments
16 made by subparagraph (A).

17 (4) RULE OF CONSTRUCTION.—Nothing in this
18 subsection, including the amendments made by this
19 subsection, precludes a drug manufacturer from tak-
20 ing any corrective action to mitigate the potential
21 for patient harm from false or misleading commu-
22 nications described in paragraph (h)(2)(A) of section
23 303 of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 353), as added by paragraph (1).

1 (5) EFFECTIVE DATE.—The amendments made
2 by paragraphs (1) and (3) shall take effect 180 days
3 after the date on which the regulations described in
4 paragraph (3)(B) are finalized.

5 (b) REPORTING REQUIREMENT.—

6 (1) IN GENERAL.—Any payment described in
7 paragraph (2) with respect to the promotion of, or
8 communications regarding, a covered drug shall be
9 treated as a payment from an applicable manufac-
10 turer to a covered recipient for purposes of section
11 1128G of the Social Security Act (42 U.S.C. 1320a–
12 7h), and shall be reported to the Secretary of Health
13 and Human Services by the drug manufacturer or
14 health care provider making the payment and made
15 publicly available by the Secretary in accordance
16 with such section 1128G.

17 (2) PAYMENTS DESCRIBED.—A payment de-
18 scribed in this paragraph is—

19 (A) a payment by a drug manufacturer to
20 a health care provider, including a telehealth
21 company or other similar entity, or social media
22 influencer; or

23 (B) a payment by a health care provider,
24 including a telehealth provider or other similar
25 entity, to a social media influencer.

1 (3) DEFINITIONS.—In this subsection—

2 (A) the terms “applicable manufacturer”
3 and “covered recipient” have the meanings
4 given such terms in section 1128G(e) of the So-
5 cial Security Act (42 U.S.C. 1320a–7h); and

6 (B) the term “covered drug” means any
7 drug, including a biological product (as defined
8 in section 351(i) of the Public Health Service
9 Act (42 U.S.C. 262(i))), for which payment is
10 available under title XVIII of the Social Secu-
11 rity Act (42 U.S.C. 1395 et seq.) or a State
12 plan under title XIX or XXI of such Act (42
13 U.S.C. 1396 et seq.; 42 U.S.C. 1397aa et seq.)
14 (or a waiver of such a plan).

15 (c) MARKET SURVEILLANCE OF PRESCRIPTION
16 DRUG ADVERTISING OR PROMOTION.—

17 (1) IN GENERAL.—The Secretary may conduct
18 market surveillance activities regarding any pro-
19 motion of prescription drugs on social media plat-
20 forms. The activities under this section may in-
21 clude—

22 (A) activities, carried out directly or by
23 contract, relating to—

24 (i) aggregating and analysis of public
25 communications (which may involve the

1 use of artificial intelligence applications),
2 including to establish any relationship be-
3 tween a manufacturer of a prescription
4 drug and individuals engaging in commu-
5 nications about such drug;

6 (ii) analytical tools to review submis-
7 sions of promotional communications;

8 (iii) engagement with representatives
9 of social media platforms on strategies and
10 opportunities to address false or mis-
11 leading promotion of prescription drugs,
12 including through methods of technology
13 or functionality to identify and assess false
14 or misleading communications; and

15 (iv) developing and disseminating pub-
16 lic facing communications and educational
17 materials and programs for prescription
18 drug manufacturers, social media plat-
19 forms, and the public, which may include
20 communications and educational materials
21 and programs regarding the Bad Ad pro-
22 gram of the Food and Drug Administra-
23 tion;

24 (B) hiring additional staff for the Office of
25 Prescription Drug Promotion of the Center for

1 Drug Evaluation and Research and the Adver-
2 tising and Promotional Labeling Branch of the
3 Center for Biologics Evaluation and Research
4 for the review of advertising or promotion of
5 prescription drugs on digital platforms, such as
6 social media, and such other purposes as the
7 Secretary determines appropriate; and

8 (C) establishing a task force, jointly with
9 the Federal Trade Commission, to coordinate
10 and enhance communication between the Fed-
11 eral Trade Commission and the Food and Drug
12 Administration related to monitoring of, and
13 compliance activities relating to, prescription
14 drug advertising or promotion.

15 (2) RULE OF CONSTRUCTION.—Nothing in
16 paragraph (1) shall be construed to affect the au-
17 thority of the Secretary to carry out activities de-
18 scribed in such paragraph pursuant to other provi-
19 sions of law.

20 (3) FDA NOTICE TO MANUFACTURERS.—The
21 Secretary may establish a process for providing in-
22 formation to the holder of an approved application
23 of a prescription drug under section 505 of this Act
24 or section 351 of the Public Health Service Act for
25 the purpose of notifying such holder of instances of

1 communications by health care providers or social
2 media influencers that fail to include information in
3 brief summary relating to side effects, contraindica-
4 tions, and effectiveness of the drug in the same
5 manner and to the same extent as such information
6 is required in prescription drug advertisements pur-
7 suant to section 502(n) of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 352(n)).

9 (4) REPORTING.—The Secretary shall—

10 (A) not later than 2 years after the date
11 of enactment of this Act, submit to Congress a
12 report on the activities carried out under this
13 subsection;

14 (B) not later than 4 years after the date
15 of enactment of this Act, submit to Congress,
16 and make publicly available, a report on the ac-
17 tivities carried out under this subsection; and

18 (C) make publicly available on the website
19 of the Food and Drug Administration notice of
20 all enforcement actions taken under paragraph
21 (h) of section 303 of the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 333), as added by
23 subsection (a).

24 (5) AUTHORIZATION OF APPROPRIATIONS.—To
25 carry out this subsection, there are authorized to be

1 appropriated \$15,000,000 for each of fiscal years
2 2025 through 2029.

3 (d) SOCIAL MEDIA INFLUENCER.—In this section,
4 the term “social media influencer” has the meaning given
5 such term in paragraph (h) of section 303 of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 333), as added
7 by subsection (a).

8 (e) SEVERABILITY.—If any provision of this Act or
9 of any amendment made by this Act, or the application
10 of such provision or amendment to any person or cir-
11 cumstance, is held to be invalid, the remainder of the pro-
12 visions of this Act and of the amendments made by this
13 Act and the remainder of the provisions of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),
15 and the application of any such provision or amendment
16 to other persons not similarly situated or to other cir-
17 cumstances, shall not be affected.

○