

112TH CONGRESS
2D SESSION

H. R. 4087

To provide for the development and dissemination of best practices to ensure that visually-impaired and blind individuals in the United States have safe, consistent, reliable, and independent access to the information in prescription drug labeling.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 24, 2012

Mr. MARKEY introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To provide for the development and dissemination of best practices to ensure that visually-impaired and blind individuals in the United States have safe, consistent, reliable, and independent access to the information in prescription drug labeling.

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 “Prescription Drug La-
5 beling Promotion Act of 2012”.

1 **SEC. 2. ACCESSIBILITY OF INFORMATION IN PRESCRIP-**
2 **TION DRUG LABELING BY VISUALLY-IM-**
3 **PAIRED AND BLIND CONSUMERS.**

4 (a) ESTABLISHMENT OF WORKING GROUP.—

5 (1) IN GENERAL.—The Secretary of Health and
6 Human Services (in this section referred to as the
7 “Secretary”) shall establish a working group (in this
8 section referred to as the “working group”) to de-
9 velop and promulgate guidance constituting best
10 practices on access to prescription drug labeling for
11 the visually impaired.

12 (2) MEMBERS.—The working group shall in-
13 clude representatives of national organizations rep-
14 resenting blind and visually impaired individuals, na-
15 tional organizations representing the elderly, and in-
16 dustry groups representing stakeholders, including
17 pharmacists, who would be impacted by such best
18 practices. Representation within the working group
19 shall be divided equally between consumer and in-
20 dustry advocates.

21 (3) GUIDANCE ON BEST PRACTICES.—The
22 working group shall promulgate, not later than 1
23 year after the date of the enactment of this Act,
24 guidance on best practices for pharmacies to ensure
25 that blind and visually impaired individuals have
26 safe, consistent, reliable, and independent access to

1 the information in the labeling of prescription drugs.
2 Such guidance shall be made available through pub-
3 lication in the Federal Register and posting on the
4 Web site of the Food and Drug Administration.

5 (4) CONSIDERATIONS.—In developing and pro-
6 mulgating such guidance on best practices, the
7 working group shall consider—

8 (A) the use of—

9 (i) Braille;

10 (ii) auditory means, such as—

11 (I) “talking bottles” that provide
12 audible label information;

13 (II) digital voice recorders at-
14 tached to the prescription drug con-
15 tainer; and

16 (III) radio frequency identifica-
17 tion (RFID) tags; and

18 (iii) enhanced visual means, such as—

19 (I) large font labels or large font
20 “duplicate” labels that are affixed or
21 matched to a prescription drug con-
22 tainer;

23 (II) high-contrast printing; and

24 (III) sans-serif font;

1 (B) whether there are technical, financial,
2 manpower, or other factors unique to phar-
3 macies with 20 or fewer retail locations which
4 may fundamentally impact the ability of such
5 pharmacies to implement the best practices;
6 and

7 (C) such other factors as the working
8 group determines to be appropriate.

9 (5) INFORMATION CAMPAIGN.—Upon the pro-
10 mulgation of the guidance on best practices, the
11 Commissioner of Food and Drugs, in consultation
12 with the working group, shall conduct an informa-
13 tional and educational program designed to inform
14 the public and pharmacists about such guidance and
15 practices.

16 (6) FACA WAIVER.—The Federal Advisory
17 Committee Act shall not apply to the working group.

18 (b) GAO STUDY.—

19 (1) IN GENERAL.—Beginning 18 months after
20 the publication of the guidance on best practices
21 under subsection (a), the Comptroller General of the
22 United States shall conduct a review of such guid-
23 ance, the extent to which pharmacies are complying
24 with such best practices, and the extent to which

1 barriers to accessible prescription drug labeling for
2 blind and visually-impaired individuals continue.

3 (2) REPORT.—Not later than September 30,
4 2016, the Comptroller General shall submit to Con-
5 gress a report on the review conducted under para-
6 graph (1). Such report shall include recommenda-
7 tions for how best to reduce the barriers blind and
8 visually-impaired individuals have to access prescrip-
9 tion drug labeling.

10 (c) DEFINITIONS.—In this section:

11 (1) The term “pharmacy” includes a pharmacy
12 that receives prescriptions, and dispenses prescrip-
13 tion drugs, through an Internet Web site.

14 (2) The term “prescription drug” means a drug
15 subject to section 503(b)(1) of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

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