

111TH CONGRESS  
1ST SESSION

# S. 1142

To amend the Federal Food, Drug, and Cosmetic Act with respect to inclusion of effectiveness information in drug and device labeling and advertising.

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## IN THE SENATE OF THE UNITED STATES

MAY 21, 2009

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

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to inclusion of effectiveness information in drug and device labeling and advertising.

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 “Informed Health Care  
5 Decision Making Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) National randomized controlled trials have  
9 found that replacing the brief summary of drug ad-

1       vertisements with a drug facts box improved con-  
2       sumer knowledge and judgments. In such trials, con-  
3       sumers who were presented with a drug facts box  
4       more accurately perceived the side effects and bene-  
5       fits of a drug, and were more than twice as likely  
6       to choose the superior drug.

7               (2)(A) In 2007, the Institute of Medicine con-  
8       ducted a workshop that highlighted that the public  
9       has a limited understanding of the benefits and risks  
10      of drugs. The workshop also highlighted that it is  
11      important to—

12                   (i) provide patients and physicians with the  
13                   best possible information for making informed  
14                   decisions about the use of pharmaceuticals;

15                   (ii) employ quantitative and standardized  
16                   approaches when trying to evaluate pharma-  
17                   ceutical benefit-risk; and

18                   (iii) develop and validate improved tools for  
19                   communicating pharmaceutical benefit-risk in-  
20                   formation to patients and physicians.

21               (B) The general agreement of the workshop  
22      was that the Food and Drug Administration should  
23      pilot test a drug facts box.

24               (3) On February 27, 2009, the Food and Drug  
25      Administration’s Risk Communication Advisory

1 Committee made the following unanimous rec-  
2 ommendations:

3 (A) The Food and Drug Administration  
4 should adopt a single standard document for  
5 communicating essential information about  
6 pharmaceuticals.

7 (B) That standard document should in-  
8 clude quantitative summaries of risks and bene-  
9 fits, along with use and precaution information.

10 (C) The Food and Drug Administration  
11 should adopt the drug facts box format as its  
12 standard.

13 **SEC. 3. PRESENTATION OF DRUG BENEFIT AND RISK IN-**  
14 **FORMATION.**

15 (a) IN GENERAL.—The Secretary of Health and  
16 Human Services (referred to in this Act as the “Sec-  
17 retary”), acting through the Commissioner of Food and  
18 Drugs, shall determine whether standardized, quantitative  
19 summaries of the benefits and risks of drugs in a tabular  
20 or drug facts box format, or any alternative format, in  
21 the labeling and print advertising of such drugs would im-  
22 prove health care decisionmaking by clinicians and pa-  
23 tients and consumers.

24 (b) REVIEW AND CONSULTATION.—In making the  
25 determination under subsection (a), the Secretary shall re-

1 view all available scientific evidence and consult with drug  
2 manufacturers, clinicians, patients and consumers, experts  
3 in health literacy, and representatives of racial and ethnic  
4 minorities.

5 (c) REPORT.—Not later than 1 year after the date  
6 of enactment of this Act, the Secretary shall submit to  
7 the Congress a report that provides—

8 (1) the determination by the Secretary under  
9 subsection (a); and

10 (2) the reasoning and analysis underlying that  
11 determination.

12 (d) AUTHORITY.—

13 (1) IN GENERAL.—If the Secretary determines  
14 under subsection (a) that standardized, quantitative  
15 summaries of the benefits and risks of drugs in a  
16 tabular or drug facts box format, or any alternative  
17 format, in the labeling and print advertising of such  
18 drugs would improve health care decisionmaking by  
19 clinicians and patients and consumers, then the Sec-  
20 retary, not later than 1 year after the date of sub-  
21 mission of the report under subsection (c), shall pro-  
22 mulgate regulations as necessary to implement such  
23 format.

24 (2) OBJECTIVE AND UP-TO-DATE INFORMA-  
25 TION.—In carrying out paragraph (1), the Secretary

1 shall ensure that the information presented in a  
2 summary described under such paragraph is objec-  
3 tive and up-to-date, and is the result of a review  
4 process that considers the totality of published and  
5 unpublished data.

6 (3) POSTING OF INFORMATION.—In carrying  
7 out paragraph (1), the Secretary shall post the in-  
8 formation presented in a summary described under  
9 such paragraph on the Internet Web site of the  
10 Food and Drug Administration.

11 **SEC. 4. STANDARDS FOR COMPARATIVE CLINICAL EFFEC-**  
12 **TIVENESS INFORMATION.**

13 (a) IN GENERAL.—The Secretary, acting through the  
14 Commissioner of Food and Drugs, shall establish and peri-  
15 odically update methodological standards and criteria for  
16 the sources of evidence and the adequacy and degree of  
17 evidence that are appropriate for inclusion of comparative  
18 clinical effectiveness information in labeling and advertise-  
19 ments under subsections (f), (n)(3), and (r) of section 502  
20 of the Federal Food, Drug, and Cosmetic Act (as amended  
21 by section 5).

22 (b) REQUIREMENTS.—The standards and criteria es-  
23 tablished under subsection (a) shall ensure that compara-  
24 tive clinical effectiveness information provides reliable and  
25 useful information that improves health care decision-

1 making, adheres to rigorous scientific standards, and is  
2 produced through a transparent process that includes con-  
3 sultation with stakeholders.

4 (c) CONSULTATION.—In carrying out subsection (a),  
5 the Secretary shall consult with manufacturers of drugs  
6 and devices, clinicians, patients and consumers, experts in  
7 health literacy, and representatives of racial and ethnic  
8 minorities.

9 (d) DEFINITION.—For purposes of this section, the  
10 term “comparative clinical effectiveness” means the clin-  
11 ical outcomes, effectiveness, safety, and clinical appro-  
12 priateness of a drug or device in comparison to 1 or more  
13 drugs or devices, respectively, approved to prevent, diag-  
14 nose, or treat the same health condition for the same pa-  
15 tient demographic subpopulation.

16 **SEC. 5. DISCLOSURE OF COMPARATIVE CLINICAL EFFEC-**  
17 **TIVENESS INFORMATION.**

18 (a) COMPARATIVE CLINICAL EFFECTIVENESS.—Sec-  
19 tion 201 of the Federal Food, Drug, and Cosmetic Act  
20 (21 U.S.C. 321) is amended by adding at the end the fol-  
21 lowing:

22 “(rr) The term ‘comparative clinical effectiveness’  
23 means the clinical outcomes, effectiveness, safety, and  
24 clinical appropriateness of a drug or device in comparison  
25 to 1 or more drugs or devices, respectively, approved to

1 prevent, diagnose, or treat the same health condition for  
2 the same patient demographic subpopulation, on the basis  
3 of research that meets standards adopted by the Secretary  
4 under section 4 of the Informed Health Care Decision  
5 Making Act.”.

6 (b) LABELING AND ADVERTISING INFORMATION.—  
7 Section 502 of the Federal Food, Drug, and Cosmetic Act  
8 (21 U.S.C. 352) is amended—

9 (1) in subsection (f), by striking “for use; and  
10 (2)” and inserting “for use; (2) such information in  
11 brief summary relating to comparative clinical effec-  
12 tiveness as shall be required in regulations which  
13 shall be issued by the Secretary in accordance with  
14 the procedure specified in section 701(a); and (3)”;

15 (2) in subsection (n)(3), by striking “and effec-  
16 tiveness” and inserting “effectiveness, and compara-  
17 tive clinical effectiveness (or a disclosure that there  
18 is no such information relating to comparative clin-  
19 ical effectiveness if another drug has been approved  
20 for the same use),”; and

21 (3) in subsection (r)—

22 (A) by striking “In the case of any” and  
23 inserting “(1) In the case of any”;

24 (B) by striking “(1) a true” and inserting  
25 “(A) a true”;

1 (C) by striking “(2) a brief” and inserting  
2 “(B) a brief”; and

3 (D) by striking “and contraindications”  
4 and inserting “contraindications, and, if appro-  
5 priate after taking into consideration the type  
6 of device, effectiveness and comparative clinical  
7 effectiveness (or a disclosure that there is no  
8 such information relating to comparative clin-  
9 ical effectiveness if another device has been ap-  
10 proved for the same use)”.

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