

104TH CONGRESS
1ST SESSION

S. 1197

To amend the Federal Food, Drug, and Cosmetic Act to facilitate the dissemination to physicians of scientific information about prescription drug therapies and devices, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 11 (legislative day, JULY 10), 1995

Mr. MACK (for himself, Mr. FRIST, Mr. D'AMATO, Mr. SHELBY, Mr. ABRAHAM, Mr. SANTORUM, Mr. DEWINE, and Mr. FAIRCLOTH) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to facilitate the dissemination to physicians of scientific information about prescription drug therapies and devices, and for other purposes.

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. FINDINGS.**

4 Congress finds that—

5 (1) fostering and protecting the highest possible
6 standards of health care for the American people re-
7 quire—

1 (A) creative scientific inquiry and informa-
2 tion exchanges in the medical sciences and the
3 industries that serve the American people;

4 (B) dissemination and debate of the results
5 of such inquiry within the medical community;
6 and

7 (C) rapid development, testing, marketing
8 approval, and accessibility of state-of-the-art
9 health care products, such as drugs, biologics,
10 and medical devices;

11 (2) traditionally, free-flowing information ex-
12 changes between health professionals and the pro-
13 ducers of health care products, with respect to po-
14 tentially beneficial new uses of existing products,
15 have been a means to achieve scientific advances and
16 medical breakthroughs;

17 (3) such information exchanges have been pro-
18 tected by law, but erroneous interpretation, applica-
19 tion, and enforcement of existing law have inhibited
20 and even foreclosed such information exchanges in
21 recent years; and

22 (4) it is imperative to the health of the Amer-
23 ican people to enact legislation to clarify the intent
24 of Congress and the existing state of the law to
25 stimulate and encourage such educational and sci-

1 entific information exchanges among industry and
2 health care practitioners.

3 **SEC. 2. INFORMATION EXCHANGE AMENDMENTS.**

4 Chapter III of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 355 et seq.) is amended by adding at the
6 end thereof the following new sections:

7 **“SEC. 311. DISSEMINATION OF TREATMENT INFORMATION**
8 **ON DRUGS AND BIOLOGICAL PRODUCTS.**

9 “(a) DISSEMINATION OF TREATMENT INFORMA-
10 TION.—

11 “(1) IN GENERAL.—Notwithstanding sections
12 301(d), 502(f), 505, and 507 and section 351 of the
13 Public Health Service Act (42 U.S.C. 262), and sub-
14 ject to the requirements of paragraph (2) and sub-
15 section (b), a person may disseminate to any person
16 that is a health care practitioner or other provider
17 of health care goods or services, a pharmacy benefit
18 manager, a health maintenance organization or
19 other managed health care organization, or a health
20 care insurer or governmental agency, written infor-
21 mation, or an oral or written summary of the writ-
22 ten information, concerning—

23 “(A) a treatment use for an investigational
24 new drug or an investigational biological prod-

1 uct approved by the Secretary for such treat-
2 ment use; or

3 “(B) a use (whether or not such use is
4 contained in the official labeling) of a new drug
5 (including any antibiotic drug) or a biological
6 product for which an approval of an application
7 filed under section 505(b), 505(j), or 507, or a
8 product license issued under the Public Health
9 Service Act, is in effect.

10 “(2) REQUIREMENTS.—A person may dissemi-
11 nate information under paragraph (1)(B) only if—

12 “(A) the information is an unabridged—

13 “(i) reprint or copy of a peer-reviewed
14 article from a scientific or medical journal
15 that is published by an organization that is
16 independent of the pharmaceutical indus-
17 try; or

18 “(ii) chapter, authored by an expert
19 or experts in the disease to which the use
20 relates, from a recognized reference text-
21 book that is published by an organization
22 that is independent of the pharmaceutical
23 industry;

24 “(B) the text of the information has been
25 approved by a continuing medical education ac-

1 crediting agency that is independent of the
2 pharmaceutical industry as part of a scientific
3 or medical educational program approved by
4 such agency;

5 “(C) the information relates to a use that
6 is recognized under Federal law for purposes of
7 third-party coverage or reimbursement, and—

8 “(i) the text of the information has
9 been approved by an organization referred
10 to in such Federal law; or

11 “(ii) the information is part of a dis-
12 ease management program or treatment
13 guideline with respect to such use; or

14 “(D) the information is an accurate and
15 truthful summary of the information described
16 in subparagraph (A), (B), or (C).

17 “(b) DISCLOSURE STATEMENT.—In order to afford
18 a full and fair evaluation of the information described in
19 subsection (a), a person disseminating the information
20 shall include a statement that discloses—

21 “(1) if applicable, that the use of a new drug
22 or biological product described in subparagraph (A)
23 or (B) of subsection (a)(1) and the information with
24 respect to the use have not been approved by the
25 Food and Drug Administration;

1 “(2) if applicable, that the information is being
2 disseminated at the expense of the sponsor of the
3 drug or biological product;

4 “(3) if applicable, that one or more authors of
5 the information being disseminated are employees of
6 or consultants to the sponsor of the drug or biological
7 product; and

8 “(4) the official labeling for the drug and bio-
9 logical product, or in the case of a treatment use of
10 an investigational drug or biological product, the in-
11 vestigator brochure and all updates thereof.

12 “(c) DEFINITION.—As used in this section, the term
13 ‘expense’ includes financial, in-kind, and other contribu-
14 tions provided for the purpose of disseminating the infor-
15 mation described in subsection (a).

16 “(d) SPECIAL RULE.—In the case of a professional
17 disagreement between the Secretary and other qualified
18 experts with respect to the application of section 502(a),
19 the Secretary may not use section 502 to prohibit the dis-
20 semination of information in the types of circumstances
21 and under the conditions set forth in subsections (a) and
22 (b).

23 **“SEC. 312. DISSEMINATION OF INFORMATION ON DEVICES.**

24 “(a) DISSEMINATION OF INFORMATION.—Notwith-
25 standing sections 301, 501(f), 501(i), 502(a), 502(f), and

1 502(o), or any other provision of law, and subject to sub-
2 sections (b) and (c), a person may disseminate to any per-
3 son that is a health care practitioner or other provider
4 of health care goods or services, a pharmacy benefit man-
5 ager, a health maintenance organization or other managed
6 health care organization, or a health care insurer or gov-
7 ernmental agency, written or oral information (including
8 information exchanged at scientific and educational meet-
9 ings, workshops, or demonstrations) relating to a use,
10 whether or not the use is described in the official labeling,
11 of a device produced by a manufacturer registered pursu-
12 ant to section 510.

13 “(b) DISCLOSURE STATEMENTS AND REQUIRE-
14 MENTS.—

15 “(1) DISCLOSURE STATEMENTS.—To the extent
16 practicable, the requirement with respect to a state-
17 ment of disclosure under subsection (b) of section
18 311 shall apply to the dissemination of written and
19 oral information under this section, except that this
20 paragraph shall not apply to the dissemination of
21 written or oral information with respect to the in-
22 tended use described in the labeling of a device.

23 “(2) ADDITIONAL REQUIREMENTS.—A person
24 may disseminate information under subsection (a)
25 only if—

1 “(A) the information is an unabridged—

2 “(i) reprint or copy of a peer-reviewed
3 article from a scientific or medical journal
4 that is published by an organization that is
5 independent of the medical device industry;
6 or

7 “(ii) chapter, authored by an expert
8 or experts in the medical specialty to which
9 the use relates, from a recognized ref-
10 erence textbook that is published by an or-
11 ganization that is independent of the medi-
12 cal device industry;

13 “(B) the information has been approved by
14 a continuing medical education accrediting
15 agency that is independent of the medical de-
16 vice industry as part of a scientific or medical
17 educational program approved by such agency;

18 “(C) the information relates to a use that
19 is recognized under Federal law for purposes of
20 third-party reimbursement, and—

21 “(i) the text of the information has
22 been approved by an organization referred
23 to in such Federal law; or

1 “(ii) the information is part of a dis-
2 ease management program or treatment
3 guideline with respect to such use; or

4 “(D) the oral or written information is—

5 “(i) part of an exchange of informa-
6 tion solely among health care practitioners,
7 health care reimbursement officials, and
8 the industry;

9 “(ii) exchanged for educational or sci-
10 entific purposes; and

11 “(iii) presented at continuing medical
12 education programs, seminars, workshops,
13 or demonstrations.

14 “(3) APPLICABILITY.—The requirements under
15 subsection (a)(1)(A) and (B) of section 311 shall not
16 apply with respect to devices.

17 “(c) INFORMATION DISSEMINATION NOT EVIDENCE
18 OF INTENDED USE.—Notwithstanding section 502(a),
19 502(f), 502(o), or any other provision of law, the written
20 or oral dissemination of information relating to a new use
21 of a device, in accordance with this section, shall not be
22 construed by the Secretary as evidence of a new intended
23 use of the device that is different from the intended use
24 of the device set forth on the official labeling of the device.
25 Such dissemination shall not be considered by the Sec-

1 retary as labeling, adulteration, or misbranding of the de-
2 vice.”.

3 **SEC. 3. PRESERVATION OF CURRENT POLICY.**

4 Nothing in this Act or the amendment made by this
5 Act shall affect the ability of manufacturers to respond
6 fully to unsolicited questions from health care practition-
7 ers and other persons about drugs, biological products, or
8 devices.

