

104TH CONGRESS
2D SESSION

H. R. 2932

To amend the Federal Food, Drug, and Cosmetic Act to revise the requirements of that Act relating to the dissemination of scientific information on drugs.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 1, 1996

Mr. BURR (for himself, Mr. COBURN, Mr. STENHOLM, Mr. UPTON, Mr. BREWSTER, Mr. BILBRAY, Mrs. LINCOLN, and Mr. HEINEMAN) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise the requirements of that Act relating to the dissemination of scientific information on 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. DISSEMINATION OF SCIENTIFIC INFORMATION.**

4 Section 505 of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 355) is amended by adding at the end the
6 following:

7 “(n)(1) The holder of an approved new drug applica-
8 tion may distribute in any manner to a health professional

1 (including a health provider or insurer) a reprint of an
2 article in an independent peer-reviewed medical textbook,
3 journal, or medical compendium which includes informa-
4 tion about the drug that is not in the package insert, if
5 the reprint is accompanied by a copy of the package insert
6 and a statement that the reprint includes information that
7 has not been approved by the Food and Drug Administra-
8 tion. Reprints distributed under this subsection shall not
9 be regulated as advertising or labeling and shall not be
10 required to be submitted to the Secretary.

11 “(2) With respect to an approved indication for a new
12 drug, and for any pharmacoeconomic information relating
13 to a drug, the Secretary shall not take action to prevent
14 the use of advertising or labeling (except the package in-
15 sert) unless the Secretary determines in writing, after an
16 informal hearing, that the advertising or labeling is likely
17 to cause misuse of the drug in a way that is unsafe or
18 ineffective.

19 “(3) For purposes of this subsection, the term ‘peer-
20 reviewed journal’ includes journals of medical societies as-
21 sociated with a certifying board of the American Board
22 of Medical Specialties or an equivalent organization in
23 health economics and such other journals as the Commis-
24 sioner shall designate by regulation. This function may not
25 be further delegated.”.

1 **SEC. 2. EFFECTIVE DATE.**

2 The amendment made by section 1 shall take effect
3 upon the date of enactment of this Act.

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