

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.

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## 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

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## 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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