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107TH CONGRESS
2D SESSION

# H. R. 5037

To require prescription drug manufacturers, packers, and distributors to disclose certain gifts provided in connection with detailing, promotional, or other marketing activities, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

JUNE 27, 2002

Mr. DEFAZIO (for himself, Mr. BROWN of Ohio, Mr. STARK, Mr. GEORGE MILLER of California, Mr. CROWLEY, Mr. FILNER, Ms. WOOLSEY, Mr. JACKSON of Illinois, Ms. NORTON, Ms. ROYBAL-ALLARD, and Mr. DOGGETT) introduced the following bill; which was referred to the Committee on Energy and Commerce

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# A BILL

To require prescription drug manufacturers, packers, and distributors to disclose certain gifts provided in connection with detailing, promotional, or other marketing activities, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Drug Company Gift Disclosure Act''.

**SEC. 2. DISCLOSURE BY PRESCRIPTION DRUG MANUFACTURERS, PACKERS, AND DISTRIBUTORS OF CERTAIN GIFTS.**

Section 503 of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 353) is amended by adding at the end the following:

''(h)(1) Each manufacturer, packer, or distributor of a drug subject to subsection (b)(1) shall disclose to the Commissioner—

''(A) not later than June 30, 2004, and each June 30 thereafter, the value, nature, and purpose of any gift provided during the preceding calendar year to any covered health entity by the manufacturer, packer, or distributor, or a representative thereof, in connection with detailing, promotional, or other marketing activities; and

''(B) not later than the date that is 6 months after the date of enactment of this subsection and each June 30 thereafter, the name and address of the individual responsible for the compliance of the manufacturer, packer, or distributor with the provisions of this subsection.

''(2) Subject to paragraph (3), the Commissioner shall make all information disclosed to the Commissioner under paragraph (1) publicly available, including by posting such information on the Internet.

''(3) The Commissioner shall keep confidential any information disclosed to or otherwise obtained by the Commissioner under this subsection that relates to a trade secret referred to in section 1905 of title 18, United States Code. The Commissioner shall provide an opportunity in the disclosure form required under paragraph (4) for a manufacturer, packer, or distributor to identify any such information.

''(4) Each disclosure under this subsection shall be made in such form and manner as the Commissioner may require.

''(5) Each manufacturer, packer, and distributor described in paragraph (1) shall be subject to a civil monetary penalty of not more than $10,000 for each violation of this subsection. Each unlawful failure to disclose shall constitute a separate violation. The provisions of paragraphs (3), (4), and (5) of section 303(g) shall apply to such a violation in the same manner as such provisions apply to a violation of a requirement of this Act that relates to devices.

''(6) For purposes of this subsection:

''(A) The term 'covered health entity' includes any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe or dispense drugs that

are subject to subsection (b)(1), in the District of Columbia or any State, commonwealth, possession, or territory of the United States.

''(B) The term 'gift' includes any gift, fee, payment, subsidy, or other economic benefit with a value of $50 or more, except that such term excludes the following:

''(i) Free samples of drugs subject to subsection (b)(1) intended to be distributed to patients.

''(ii) The payment of reasonable compensation and reimbursement of expenses in connection with any bona fide clinical trial conducted in connection with a research study designed to answer specific questions about drugs, devices, new therapies, or new ways of using known treatments.

''(iii) Any scholarship or other support for medical students, residents, or fellows selected by a national, regional, or specialty medical or other professional association to attend a significant educational, scientific, or policy-making conference of the association.''.

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