

108TH CONGRESS
1ST SESSION

H. R. 757

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.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2003

Mr. DEFAZIO (for himself, Mr. BROWN of Ohio, Mr. STARK, Mr. CROWLEY, Ms. NORTON, Mr. LANTOS, Mr. BERRY, Ms. DELAURO, Mr. DAVIS of Illinois, Mr. GEORGE MILLER of California, Mr. MICHAUD, Mr. WYNN, Mr. McDERMOTT, Mr. GRIJALVA, Ms. WOOLSEY, Mr. FROST, Mr. DOGGETT, Mr. SANDERS, Ms. ROYBAL-ALLARD, Mr. LIPINSKI, Mr. HINCHEY, and Ms. SLAUGHTER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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.

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 “Drug Company Gift
5 Disclosure Act”.

1 **SEC. 2. DISCLOSURE BY PRESCRIPTION DRUG MANUFAC-**
2 **TURERS, PACKERS, AND DISTRIBUTORS OF**
3 **CERTAIN GIFTS.**

4 Section 503 of the Federal Food, Drug, and Cos-
5 metics Act (21 U.S.C. 353) is amended by adding at the
6 end the following:

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

10 “(A) not later than June 30, 2004, and each
11 June 30 thereafter, the value, nature, and purpose
12 of any—

13 “(i) gift provided during the preceding cal-
14 endar year to any covered health entity by the
15 manufacturer, packer, or distributor, or a rep-
16 resentative thereof, in connection with detailing,
17 promotional, or other marketing activities; and

18 “(ii) cash rebate, discount, or any other fi-
19 nancial consideration provided during the pre-
20 ceding calendar year to any pharmaceutical
21 benefit manager by the manufacturer, packer,
22 or distributor, or a representative thereof, in
23 connection with detailing, promotional, or other
24 marketing activities; and

25 “(B) not later than the date that is 6 months
26 after the date of enactment of this subsection and

1 each June 30 thereafter, the name and address of
2 the individual responsible for the compliance of the
3 manufacturer, packer, or distributor with the provi-
4 sions of this subsection.

5 “(2) Subject to paragraph (3), the Commissioner
6 shall make all information disclosed to the Commissioner
7 under paragraph (1) publicly available, including by post-
8 ing such information on the Internet.

9 “(3) The Commissioner shall keep confidential any
10 information disclosed to or otherwise obtained by the Com-
11 missioner under this subsection that relates to a trade se-
12 cret referred to in section 1905 of title 18, United States
13 Code. The Commissioner shall provide an opportunity in
14 the disclosure form required under paragraph (4) for a
15 manufacturer, packer, or distributor to identify any such
16 information.

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

20 “(5) Each manufacturer, packer, and distributor de-
21 scribed in paragraph (1) shall be subject to a civil mone-
22 tary penalty of not more than \$10,000 for each violation
23 of this subsection. Each unlawful failure to disclose shall
24 constitute a separate violation. The provisions of para-
25 graphs (3), (4), and (5) of section 303(g) shall apply to

1 such a violation in the same manner as such provisions
2 apply to a violation of a requirement of this Act that re-
3 lates to devices.

4 “(6) For purposes of this subsection:

5 “(A) The term ‘covered health entity’ includes
6 any physician, hospital, nursing home, pharmacist,
7 health benefit plan administrator, or any other per-
8 son authorized to prescribe or dispense drugs that
9 are subject to subsection (b)(1), in the District of
10 Columbia or any State, commonwealth, possession,
11 or territory of the United States.

12 “(B) The term ‘gift’ includes any gift, fee, pay-
13 ment, subsidy, or other economic benefit with a
14 value of \$50 or more, except that such term excludes
15 the following:

16 “(i) Free samples of drugs subject to sub-
17 section (b)(1) intended to be distributed to pa-
18 tients.

19 “(ii) The payment of reasonable compensa-
20 tion and reimbursement of expenses in connec-
21 tion with any bona fide clinical trial conducted
22 in connection with a research study designed to
23 answer specific questions about drugs, devices,
24 new therapies, or new ways of using known
25 treatments.

1 “(iii) Any scholarship or other support for
2 medical students, residents, or fellows selected
3 by a national, regional, or specialty medical or
4 other professional association to attend a sig-
5 nificant educational, scientific, or policy-making
6 conference of the association.”.

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