

110TH CONGRESS  
1ST SESSION

# H. R. 3023

To require the manufacturers, packers, and distributors of prescription drugs and medical devices 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

JULY 12, 2007

Mr. DEFAZIO (for himself, Mr. STARK, Mr. WAXMAN, Mr. CHANDLER, and Mr. HINCHEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To require the manufacturers, packers, and distributors of prescription drugs and medical devices 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 and Medical De-  
5       vice Company Gift Disclosure Act”.

1   **SEC. 2. DISCLOSURE OF CERTAIN GIFTS BY MANUFACTUR-**  
2                   **ERS, PACKERS, AND DISTRIBUTORS OF PRE-**  
3                   **SCRIPTION DRUGS AND MEDICAL DEVICES.**

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) or of a device shall  
9   disclose to the Commissioner—

10       “(A) not later than June 30, 2007, and each  
11   June 30 thereafter, the value, nature, and purpose  
12   of any—

13       “(i) gift provided, directly or indirectly,  
14   during the preceding calendar year to any cov-  
15   ered health entity by the manufacturer, packer,  
16   or distributor, or a representative or agent  
17   thereof, in connection with detailing, pro-  
18   motional, or other marketing activities; and

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

1           “(B) not later than the date that is 6 months  
2           after the date of enactment of this subsection and  
3           each June 30 thereafter, the name and address of  
4           the individual responsible for the compliance of the  
5           manufacturer, packer, or distributor with the provi-  
6           sions of this subsection.

7           “(2) Each disclosure under this subsection shall be  
8           made in such form and manner as the Commissioner may  
9           require.

10          “(3) For purposes of this subsection:

11           “(A) The term ‘covered health entity’ includes,  
12           but is not limited to, any physician, nurse, therapist,  
13           hospital, nursing home, pharmacist, health benefit  
14           plan administrator, or any other person authorized  
15           to prescribe or dispense drugs that are subject to  
16           subsection (b)(1), in the District of Columbia or any  
17           State, commonwealth, possession, or territory of the  
18           United States. Such term includes an individual who  
19           is not directly employed by the drug or device manu-  
20           facturer, packer, distributor, representative, or  
21           agent.

22           “(B) The term ‘gift’ includes any gift, fee, pay-  
23           ment, subsidy, amenity, object, service or other eco-  
24           nomic benefit, except that such term excludes the  
25           following:

1                   “(i) Free samples of drugs subject to sub-  
2                   section (b)(1) intended to be distributed to pa-  
3                   tients free of charge.

4                   “(ii) The payment of reasonable compensa-  
5                   tion and reimbursement of expenses in connec-  
6                   tion with any bona fide clinical trial conducted  
7                   in connection with a research study designed to  
8                   answer specific questions about drugs, devices,  
9                   new therapies, or new ways of using known  
10                  treatments.

11                  “(iii) Any scholarship or other support for  
12                  medical students, residents, or fellows selected  
13                  by a national, regional, or specialty medical or  
14                  other professional association to attend a sig-  
15                  nificant educational, scientific, or policy-making  
16                  conference of the association.

17                  “(4) With respect to gifts, paragraph (1) shall only  
18                  apply if the total value of any gift or gifts provided during  
19                  the applicable calendar year is fifty dollars or more.

20                  “(5) Subject to paragraph (6), the Commissioner  
21                  shall make all information disclosed to the Commissioner  
22                  under paragraph (1) publicly available, including by post-  
23                  ing such information on the Internet.

24                  “(6) The Commissioner shall keep confidential any  
25                  information disclosed to or otherwise obtained by the Com-

1 missioner under this subsection that relates to a trade se-  
2 cret referred to in section 1905 of title 18, United States  
3 Code. The Commissioner shall provide an opportunity in  
4 the disclosure form required under paragraph (2) for a  
5 manufacturer, packer, or distributor to identify any such  
6 information.

7       “(7) Each manufacturer, packer, or distributor de-  
8 scribed in paragraph (1) shall be subject to a civil mone-  
9 tary penalty of not more than \$10,000 for each violation  
10 of this subsection. Each unlawful failure to disclose shall  
11 constitute a separate violation. The provisions of para-  
12 graphs (3), (4), and (5) of section 303(f) shall apply to  
13 such a violation in the same manner as such provisions  
14 apply to a violation of a requirement of this Act that re-  
15 lates to devices.

16       “(8)(A) The Commissioner shall have authority to in-  
17 vestigate compliance with this subsection.

18       “(B) If, after carrying out an investigation under this  
19 paragraph, the Commissioner has reasonable cause to be-  
20 lieve that a report required under this subsection has not  
21 been filed in accordance with the provisions of this section,  
22 the Commissioner may petition the United States District  
23 Court in which the responsible party resides or transacts

- 1 business, for an order requiring submission of a report and
- 2 such other relief as the Court considers appropriate.”.

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