

[COMMITTEE PRINT]

[SHOWING TEXT OF COMMITTEE PRINT AS APPROVED BY SUBCOMMITTEE ON HEALTH ON JUNE 19, 2007]

110TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act with respect to conflicts of interest, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

M____. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to conflicts of interest, 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. CONFLICTS OF INTEREST.**

4 (a) IN GENERAL.—Subchapter A of chapter VII of
5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371
6 et seq.) is amended by inserting at the end the following:

7 **“SEC. 712. CONFLICTS OF INTEREST.**

8 **“(a) DEFINITIONS.—**For purposes of this section:

1 “(1) ADVISORY COMMITTEE.—The term ‘advi-
2 sory committee’ means an advisory committee under
3 the Federal Advisory Committee Act that provides
4 advice or recommendations to the Secretary regard-
5 ing activities of the Food and Drug Administration.

6 “(2) FINANCIAL INTEREST.—The term ‘finan-
7 cial interest’ means a financial interest under section
8 208(a) of title 18, United States Code.

9 “(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

10 “(1) RECRUITMENT.—

11 “(A) IN GENERAL.—Given the importance
12 of advisory committees to the review process at
13 the Food and Drug Administration, the Sec-
14 retary, through the Office of Women’s Health,
15 the Office of Orphan Product Development, the
16 Office of Pediatric Therapeutics, and other of-
17 fices within the Food and Drug Administration
18 with relevant expertise, shall develop and imple-
19 ment strategies on effective outreach to poten-
20 tial members of advisory committees at univer-
21 sities, colleges, other academic research centers,
22 professional and medical societies, and patient
23 and consumer groups. The Secretary shall seek
24 input from professional medical and scientific
25 societies to determine the most effective infor-

1 mational and recruitment activities. The Sec-
2 retary shall also take into account the advisory
3 committees with the greatest number of vacan-
4 cies.

5 “(B) RECRUITMENT ACTIVITIES.—The re-
6 cruitment activities under subparagraph (A)
7 may include—

8 “(i) advertising the process for becom-
9 ing an advisory committee member at med-
10 ical and scientific society conferences;

11 “(ii) making widely available, includ-
12 ing by using existing electronic commu-
13 nications channels, the contact information
14 for the Food and Drug Administration
15 point of contact regarding advisory com-
16 mittee nominations; and

17 “(iii) developing a method through
18 which an entity receiving funding from the
19 National Institutes of Health, the Agency
20 for Healthcare Research and Quality, the
21 Centers for Disease Control and Preven-
22 tion, or the Veterans Health Administra-
23 tion can identify a person who the Food
24 and Drug Administration can contact re-

1 garding the nomination of individuals to
2 serve on advisory committees.

3 “(2) EVALUATION AND CRITERIA.—When con-
4 sidering a term appointment to an advisory com-
5 mittee, the Secretary shall review the expertise of
6 the individual and the financial disclosure report
7 filed by the individual pursuant to the Ethics in
8 Government Act of 1978 for each individual under
9 consideration for the appointment, so as to reduce
10 the likelihood that an appointed individual will later
11 require a written determination as referred to in sec-
12 tion 208(b)(1) of title 18, United States Code, a
13 written certification as referred to in section
14 208(b)(3) of title 18, United States Code, or a waiv-
15 er as referred to in subsection (c)(3) of this section
16 for service on the committee at a meeting of the
17 committee.

18 “(3) PARTICIPATION OF GUEST EXPERT WITH
19 FINANCIAL INTEREST.—Notwithstanding any other
20 provision of this section, an individual with a finan-
21 cial interest with respect to any matter considered
22 by an advisory committee may be allowed to partici-
23 pate in a meeting of an advisory committee as a
24 guest expert if the Secretary determines that the in-
25 dividual has particular expertise required for the

1 meeting. An individual participating as a guest ex-
2 pert may provide information and expert opinion,
3 but shall not participate in the discussion or voting
4 by the members of the advisory committee.

5 “(c) GRANTING AND DISCLOSURE OF WAIVERS.—

6 “(1) IN GENERAL.—Prior to a meeting of an
7 advisory committee regarding a ‘particular matter’
8 (as that term is used in section 208 of title 18,
9 United States Code), each member of the committee
10 who is a full-time Government employee or special
11 Government employee shall disclose to the Secretary
12 financial interests in accordance with subsection (b)
13 of such section 208.

14 “(2) FINANCIAL INTEREST OF ADVISORY COM-
15 MITTEE MEMBER OR FAMILY MEMBER.—No member
16 of an advisory committee may vote with respect to
17 any matter considered by the advisory committee if
18 such member (or an immediate family member of
19 such member) has a financial interest that could be
20 affected by the advice given to the Secretary with re-
21 spect to such matter, excluding interests exempted
22 in regulations issued by the Director of the Office of
23 Government Ethics as too remote or inconsequential
24 to affect the integrity of the services of the Govern-

1 ment officers or employees to which such regulations
2 apply.

3 “(3) WAIVER.—The Secretary may grant a
4 waiver of the prohibition in paragraph (2) if such
5 waiver is necessary to afford the advisory committee
6 essential expertise.

7 “(4) LIMITATIONS.—

8 “(A) ONE WAIVER PER COMMITTEE MEET-
9 ING.—Notwithstanding any other provision of
10 this section, with respect to each advisory com-
11 mittee, the Secretary shall not grant more than
12 1 waiver under paragraph (3) per committee
13 meeting.

14 “(B) SCIENTIFIC WORK.—The Secretary
15 may not grant a waiver under paragraph (3)
16 for a member of an advisory committee when
17 the member’s own scientific work is involved.

18 “(5) DISCLOSURE OF WAIVER.—Notwith-
19 standing section 107(a)(2) of the Ethics in Govern-
20 ment Act (5 U.S.C. App.), the following shall apply:

21 “(A) 15 OR MORE DAYS IN ADVANCE.—As
22 soon as practicable, but in no case later than
23 15 days prior to a meeting of an advisory com-
24 mittee to which a written determination as re-
25 ferred to in section 208(b)(1) of title 18, United

1 States Code, a written certification as referred
2 to in section 208(b)(3) of title 18, United
3 States Code, or a waiver as referred to in para-
4 graph (3) applies, the Secretary shall disclose
5 (other than information exempted from disclo-
6 sure under section 552 of title 5, United States
7 Code, and section 552a of title 5, United States
8 Code (popularly known as the Freedom of In-
9 formation Act and the Privacy Act of 1974, re-
10 spectively)) on the Internet website of the Food
11 and Drug Administration—

12 “(i) the type, nature, and magnitude
13 of the financial interests of the advisory
14 committee member to which such deter-
15 mination, certification, or waiver applies;
16 and

17 “(ii) the reasons of the Secretary for
18 such determination, certification, or waiv-
19 er.

20 “(B) LESS THAN 30 DAYS IN ADVANCE.—
21 In the case of a financial interest that becomes
22 known to the Secretary less than 30 days prior
23 to a meeting of an advisory committee to which
24 a written determination as referred to in section
25 208(b)(1) of title 18, United States Code, a

1 written certification as referred to in section
2 208(b)(3) of title 18, United States Code, or a
3 waiver as referred to in paragraph (3) applies,
4 the Secretary shall disclose (other than infor-
5 mation exempted from disclosure under section
6 552 of title 5, United States Code, and section
7 552a of title 5, United States Code) on the
8 Internet website of the Food and Drug Admin-
9 istration, the information described in clauses
10 (i) and (ii) of subparagraph (A) as soon as
11 practicable after the Secretary makes such de-
12 termination, certification, or waiver, but in no
13 case later than the date of such meeting.

14 “(d) PUBLIC RECORD.—The Secretary shall ensure
15 that the public record and transcript of each meeting of
16 an advisory committee includes the disclosure required
17 under subsection (c)(5) (other than information exempted
18 from disclosure under section 552 of title 5, United States
19 Code, and section 552a of title 5, United States Code).

20 “(e) ANNUAL REPORT.—Not later than February 1
21 of each year, the Secretary shall submit to the Committee
22 on Appropriations and the Committee on Health, Edu-
23 cation, Labor, and Pensions of the Senate, and the Com-
24 mittee on Appropriations and the Committee on Energy

1 and Commerce of the House of Representatives a report
2 that describes—

3 “(1) with respect to the fiscal year that ended
4 on September 30 of the previous year, the number
5 of vacancies on each advisory committee, the number
6 of nominees received for each committee, and the
7 number of such nominees willing to serve;

8 “(2) with respect to such year, the aggregate
9 number of disclosures required under subsection
10 (c)(5) for each meeting of each advisory committee
11 and the percentage of individuals to whom such dis-
12 closures did not apply who served on such committee
13 for each such meeting;

14 “(3) with respect to such year, the number of
15 times the disclosures required under subsection
16 (c)(5) occurred under subparagraph (B) of such sub-
17 section; and

18 “(4) how the Secretary plans to reduce the
19 number of vacancies reported under paragraph (1)
20 during the fiscal year following such year, and mech-
21 anisms to encourage the nomination of individuals
22 for service on an advisory committee, including those
23 who are classified by the Food and Drug Adminis-
24 tration as academicians or practitioners.

1 “(f) PERIODIC REVIEW OF GUIDANCE.—Not less
2 than once every 5 years, the Secretary shall review guid-
3 ance of the Food and Drug Administration regarding con-
4 flict of interest waiver determinations with respect to advi-
5 sory committees and update such guidance as necessary.”.

6 (b) CONFORMING AMENDMENT.—Section 505(n) of
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 355(n)) is amended by—

9 (1) striking paragraph (4); and

10 (2) redesignating paragraphs (5), (6), (7), and
11 (8) as paragraphs (4), (5), (6), and (7), respectively.

12 (c) EFFECTIVE DATE.—The amendments made by
13 this section shall take effect on October 1, 2007.