

TITLE VII--CONFLICTS OF INTEREST

SEC. 701. CONFLICTS OF INTEREST.

(a) In General.--Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by inserting at the end the following:

"SEC. 712. <<NOTE: 21 USC 379d-1.>> CONFLICTS OF INTEREST.

"(a) Definitions.--For purposes of this section:

"(1) Advisory committee.--The term 'advisory committee' means an advisory committee under the Federal Advisory Committee Act that provides advice or recommendations to the Secretary regarding activities of the Food and Drug Administration.

"(2) Financial interest.--The term 'financial interest' means a financial interest under section 208(a) of title 18, United States Code.

"(b) Appointments to Advisory Committees.--

"(1) Recruitment.--

"(A) In general.--The Secretary shall--

"(i) develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient and consumer groups;

"(ii) seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities; and

"(iii) take into account the advisory committees with the greatest number of vacancies.

"(B) Recruitment activities.--The recruitment activities under subparagraph (A) may include--

"(i) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

"(ii) making widely available, including by using existing electronic communications channels, the contact information for the Food and Drug Administration point of contact regarding advisory committee nominations; and

"(iii) developing a method through which an entity receiving funding from the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, or the Veterans Health Administration can identify a person who the Food and Drug Administration can contact regarding the nomination of individuals to serve on advisory committees.

"(2) Evaluation and criteria.--When considering a term appointment to an advisory committee, the Secretary shall review the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration [[Page 121 STAT. 901]] for the appointment, so as to reduce the likelihood that an appointed individual will later require a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in subsection (c)(2) of this section for service on the committee at a meeting of the committee.

"(c) Disclosures; Prohibitions on Participation; Waivers.--

"(1) Disclosure of financial interest.--Prior to a meeting of an advisory committee regarding a 'particular matter' (as that term is used in section 208 of title 18, United States Code), each member of the committee who is a full-time Government employee or special Government employee shall disclose to the Secretary financial interests in accordance with subsection (b) of such section 208.

"(2) Prohibitions and waivers on participation.--

"(A) In general.--Except as provided under subparagraph (B), a member of an advisory committee may not participate with respect to a particular matter considered in an advisory committee meeting if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such

matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the Government officers or employees to which such regulations apply.

"(B) Waiver.--If the Secretary determines it necessary to afford the advisory committee essential expertise, the Secretary may grant a waiver of the prohibition in subparagraph (A) to permit a member described in such subparagraph to--

"(i) participate as a non-voting member with respect to a particular matter considered in a committee meeting; or

"(ii) participate as a voting member with respect to a particular matter considered in a committee meeting.

"(C) Limitation on waivers and other exceptions.--

"(i) Definition.--For purposes of this subparagraph, the term 'exception' means each of the following with respect to members of advisory committees:

"(I) A waiver under section 505(n)(4) (as in effect on the day before the date of the enactment of the Food and Drug Administration Amendments Act of 2007).

"(II) A written determination under section 208(b) of title 18, United States Code.

"(III) A written certification under section 208(b)(3) of such title.

"(ii) Determination of total number of members slots and member exceptions during fiscal year 2007.--The Secretary shall determine--

"(I)(aa) for each meeting held by any advisory committee during fiscal year 2007, the number of members who participated in the meeting; and [[Page 121 STAT. 902]]

"(bb) the sum of the respective numbers determined under item (aa) (referred to in this subparagraph as the "total number of 2007 meeting slots"); and

"(II)(aa) for each meeting held by any advisory committee during fiscal year 2007, the number of members who received an exception for the meeting; and

"(bb) the sum of the respective numbers determined under item (aa) (referred to in this subparagraph as the "total number of 2007 meeting exceptions").

"(iii) Determination of percentage regarding exceptions during fiscal year 2007.--The Secretary shall determine the percentage constituted by--

"(I) the total number of 2007 meeting exceptions; divided by

"(II) the total number of 2007 meeting slots.

"(iv) Limitation for fiscal years 2008 through 2012.--The number of exceptions at the Food and Drug Administration for members of advisory committees for a fiscal year may not exceed the following:

"(I) For fiscal year 2008, 95 percent of the percentage determined under clause (iii) (referred to in this clause as the "base percentage").

"(II) For fiscal year 2009, 90 percent of the base percentage.

"(III) For fiscal year 2010, 85 percent of the base percentage.

"(IV) For fiscal year 2011, 80 percent of the base percentage.

"(V) For fiscal year 2012, 75 percent of the base percentage.

"(v) Allocation of exceptions.--The exceptions authorized under clause (iv) for a fiscal year may be allocated within the centers or other organizational units of the Food and Drug Administration as determined appropriate by the Secretary.

"(3) Disclosure of <<NOTE: Applicability. Website.>> waiver.--Notwithstanding section 107(a)(2) of the Ethics in Government Act (5 U.S.C. App.), the following shall apply:

"(A) 15 or more days in advance.--As soon as practicable, but (except as provided in subparagraph (B)) not later than 15 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (2)(B) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code (popularly known as the Freedom of Information Act and the Privacy Act of 1974, respectively)) on the Internet Web site of the Food and Drug Administration--

"(i) the type, nature, and magnitude of the financial interests of the advisory committee member to [[Page 121 STAT. 903]] which such determination, certification, or waiver applies; and

"(ii) the reasons of the Secretary for such determination, certification, or waiver.

"(B) Less than 30 days in advance.--In the case of a financial interest that becomes known to the Secretary less than 30 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (2)(B) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code) on the Internet Web site of the Food and Drug Administration, the information described in clauses (i) and (ii) of subparagraph (A) as soon as practicable after the Secretary makes such determination, certification, or waiver, but in no case later than the date of such meeting.

"(d) Public Record.--The Secretary shall ensure that the public record and transcript of each meeting of an advisory committee includes the disclosure required under subsection (c)(3) (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code).

"(e) Annual Report.--Not later than February 1 of each year, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report that describes--

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

"(2) with respect to such year, the aggregate number of disclosures required under subsection (c)(3) for each meeting of each advisory committee and the percentage of individuals to whom such disclosures did not apply who served on such committee for each such meeting;

"(3) with respect to such year, the number of times the disclosures required under subsection (c)(3) occurred under subparagraph (B) of such subsection; and

"(4) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.

"(f) Periodic Review of Guidance.--Not less than once every 5 years, the Secretary shall review guidance of the Food and Drug Administration regarding conflict of interest waiver determinations with respect to advisory committees and update such guidance as necessary."

(b) Conforming Amendments.--Section 505(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(n)) is amended by--

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(1) striking paragraph (4); and

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

(c) Effective <<NOTE: 21 USC 355 note.>> Date.--The amendments made by this section shall take effect on October 1, 2007.