

Report to Congress

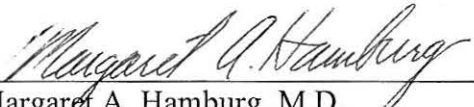
Food and Drug Administration Safety and Innovation Act of 2012

Section 712 (e) of the Federal Food, Drug, and Cosmetic Act

**Fiscal Year 2014 Annual Report on FDA Advisory Committee
Vacancies and Public Disclosures**

Department of Health and Human Services

Food and Drug Administration



Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Date 1/30/15

EXECUTIVE SUMMARY

This report is required under section 1142 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, which amends section 712(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDASIA requires the Food and Drug Administration (FDA or the Agency) to provide information on its advisory committee vacancies and public disclosures of information for fiscal year (FY) 2014. The reporting information was first mandated by the Food and Drug Administration Amendments Act of 2007, section 712, and subsequently modified by FDASIA.

As required in the statute, this report describes:

- the number of persons nominated for participation at meetings for each advisory committee;
- the number of persons so nominated and willing to serve;
- the number of vacancies on each advisory committee;
- the number of persons contacted for service as members on each advisory committee meeting for each advisory committee;
- the number of persons contacted for service as members on each advisory committee meeting for each advisory committee who did not participate because of the potential for such participation to constitute a disqualifying financial interest under 18 U.S.C. 208;
- the number of persons contacted for service as members on each advisory committee meeting for each advisory committee who did not participate because of reasons other than the potential for such participation to constitute a disqualifying financial interest under 18 U.S.C. 208;
- the number of members attending meetings for each advisory committee; and
- the aggregate number of waiver disclosures and the percentage of individuals who served on a committee for each meeting to whom waiver disclosures did not apply.

Some highlights of FY 2014 include:

- FDA continues to decrease the vacancies on advisory committees and has a current vacancy percentage of 15 percent, which is a decrease from previous years;
- FDA granted waivers under 18 USC 208(b)(3) for 0.26 percent of meeting participants (waivers granted to only 3 out of 1,115 meeting participants);
- FDA found that 5 percent of the total number of persons contacted to serve on an advisory committee did not participate because of the potential for conflicts of interest for such participation as determined by the Agency (1,963 total contacted; 107 not serving due to potential conflicts of interest); and
- FDA launched its first Membership Nomination Web Portal, an Internet-based application system. The portal enables nominees to submit their entire application for membership on an advisory committee from FDA's website, creating a paperless, streamlined process that will enable the Agency to accept, evaluate, and ultimately nominate individuals for membership in a more timely fashion.

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Background

Section 712(e) of the FD&C Act¹ requires FDA to report annually on its advisory committee vacancies and public disclosures of information. Specifically, section 712(e)² requires a report that describes:

(1) IN GENERAL.—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—

(A) with respect to the fiscal year that ended on September 30 of the previous year, the number of persons nominated for participation at meetings for each advisory committee, the number of persons so nominated and willing to serve, the number of vacancies on each advisory committee, and the number of persons contacted for service as members on each advisory committee meeting for each advisory committee who did not participate because of the potential for such participation to constitute a disqualifying financial interest under section 208 of title 18, United States Code;

(B) with respect to such year, the number of persons contacted for services as members on each advisory committee meeting for each advisory committee who did not participate because of reasons other than the potential for such participation to constitute a disqualifying financial interest under section 208 of title 18, United States Code;

(C) with respect to such year, the number of members attending meetings for each advisory committee; and

(D) with respect to such year, the aggregate number of disclosures required under subsection (d) and the percentage of individuals to whom such disclosures did not apply who served on such committee.

Reporting Period

This report covers the period from October 1, 2013, through September 30, 2014.

Scope of the FY 2014 Annual Report

In response to the information to be reported under section 712(e)(1)(A), Table 1 presents the data on the number of vacancies, the number of nominees received,³ and the number of such nominees willing to serve⁴ in FY 2014, for each advisory committee.

¹ 21 U.S.C. 379d-1(e). This annual report requirement was added by the Food and Drug Administration Amendments Act of 2007 (FDAAA), signed into law on September 27, 2007, and amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), effective October 1, 2012. Title VII of FDAAA added new conflict of interest provisions applicable to FDA advisory committees, effective October 1, 2007.

² References to “sections” in this report are to sections of the FD&C Act unless otherwise specified.

³ FDA considers a nominee as “received” when the submission includes all of the following information for the nominee: complete *curriculum vitae*, a current address and telephone number, the advisory committee(s) or advisory panel(s) for which the nominee is recommended, and a written confirmation that the nominee is aware of the nomination.

⁴ See section 712(c)(1)(B) of the FD&C Act. The nominees that FDA received were counted as “willing to serve” if a review of the submission indicated that the nominee appeared to meet qualifications to serve and the nominee confirmed his/her willingness to serve after being contacted by FDA and informed of the committee requirements for service, including conflict of interest requirements.

The number of vacancies on an FDA advisory committee may vary within any given year depending on when openings are filled and when new vacancies occur. In order to provide a complete picture of this dynamic process, Table 1 lists the total number of authorized member positions as described in the committee charter, the total number of vacancies for each advisory committee at the start of FY 2014, the number of new vacancies during FY 2014, and the number of these vacancies filled during FY 2014. FDA continues to decrease the vacancies on advisory committees and has a current vacancy percentage of 15 percent, which is a decrease from previous years.

Table 1 - 712(e)(1)(A) Pre-existing Vacancies, New Vacancies, Nominees Received, and Nominees Willing To Serve - FY 2014

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/13	Vacancies as of 9/30/13	New Vacancies during reporting period (10/01/13-9/30/14)	Vacancies Filled (10/01/13-9/30/14)	Authorized Membership as of 9/30/14	Vacancies as of 9/30/14	Nominees Received (10/01/13-9/30/14)	Nominees Willing to Serve (10/1/13-9/30/14)
Total All Offices/Centers	620	90 [**77]	145	122	595	100	545	184

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/13	Vacancies as of 9/30/13	New Vacancies during reporting period (10/01/13-9/30/14)	Vacancies Filled (10/01/13-9/30/14)	Authorized Membership as of 9/30/14	Vacancies as of 9/30/14	Nominees Received (10/01/13-9/30/14)	Nominees Willing to Serve (10/01/13-9/30/14)
OFFICE OF THE COMMISSIONER	52	7	9	12	52	4	89	25
Science Board to the FDA	21	2	4	5	21	1	62	10
Pediatric Advisory Committee	16	3	4	4	16	3	14	7
Risk Communication Advisory Committee	15	2	1	3	15	0	13	8
CENTER FOR BIOLOGICS EVALUATION & RESEARCH	71	0	21	14	71	7	24	21
Allergenic Products	10	0	3	3	10	0	4	4
Blood Products	18	0	5	2	18	3	3	3
Cellular, Tissue, & Gene Therapies	14	0	6	4	14	2	13	10
Transmissible Spongiform Encephalopathies	16	0	2	0	16	2	1	1
Vaccines and Related Biological Products	13	0	5	5	13	0	3	3
CENTER FOR DRUG EVALUATION AND RESEARCH	257	64 [**51]	45	47	232	49	273	44
Anesthetic and Life Support Drugs	14	1	5	6	12	0	8	6
Anti-Infective Drugs	14	1	1	2	14	0	6	1
Antiviral Drugs	14	0	4	4	14	0	2	0
Arthritis	12	6	2	8	12	0	13	7
Cardiovascular and Renal Drugs	12	2	2	0	12	4	12	1
Dermatologic and Ophthalmic Drugs	16	11	3	3	16	11	10	0
*Drug Safety and Risk Management	14	0	3	0	12	3	22	0
Endocrinologic and Metabolic Drugs	12	1	4	1	12	4	13	4
Gastrointestinal Drugs	12	2	2	4	12	0	3	2

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/13	Vacancies as of 9/30/13	New Vacancies during reporting period (10/01/13-9/30/14)	Vacancies Filled (10/01/13-9/30/14)	Authorized Membership as of 9/30/14	Vacancies as of 9/30/14	Nominees Received (10/01/13-9/30/14)	Nominees Willing to Serve (10/01/13-9/30/14)
Medical Imaging Drugs	13	1	1	2	13	0	3	1
Nonprescription Drugs	15	0	2	1	15	1	7	0
Oncologic Drugs	14	0	5	2	14	3	14	10
Peripheral and Central Nervous System Drugs	12	1	4	5	10	0	6	3
Pharmaceutical Science and Clinical Pharmacology	30	185	0	0	17	5	16	2
**Pharmacy Compounding	13	13	0	0	13	13	115	3
****Psychopharmacologic Drugs	12	3	2	2	10	3	11	1
Pulmonary-Allergy Drugs	14	4	2	6	12	0	5	3
*****Reproductive Health Drugs/Bone, Reproductive and Urologic Drugs	14	0	3	1	12	2	7	0
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	202	17	60	39	202	38	86	64
Device Good Manufacturing Practice Advisory Committee	9	1	2	1	9	2	10	0
Medical Devices Advisory Committee (Comprised of 18 Panels)								
- Anesthesiology and Respiratory Therapy Devices Panel	9	0	4	0	9	4	6	6
- Circulatory System Devices Panel	9	2	1	2	9	1	8	8
- Clinical Chemistry and Clinical Toxicology Devices Panel	9	0	2	0	9	2	2	2
- Dental Products Panel	10	1	3	3	10	1	6	3
- Ear, Nose, and Throat Devices Panel	9	1	3	4	9	0	2	2
- Gastroenterology-Urology Devices Panel	9	0	2	2	9	0	3	1
- General and Plastic Surgery Devices Panel	9	0	2	0	9	2	1	0
- General Hospital and Personal Use Devices Panel	9	0	4	3	9	1	6	6
- Hematology and Pathology Devices Panel	9	0	4	1	9	3	3	2
- Immunology Devices Panel	9	1	3	1	9	3	1	1
- Medical Devices Dispute Resolution Panel	5	0	1	1	5	0	6	1
- Microbiology Devices Panel	9	2	3	4	9	1	3	3
- Molecular and Clinical Genetics Panel	9	2	2	4	9	0	10	10
- Neurological Devices Panel	9	0	2	2	9	0	3	3
- Obstetrics-Gynecology Devices Panel	9	0	5	0	9	5	6	6
- Ophthalmic Devices Panel	9	0	3	3	9	0	3	3

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/13	Vacancies as of 9/30/13	New Vacancies during reporting period (10/01/13-9/30/14)	Vacancies Filled (10/01/13-9/30/14)	Authorized membership as of 9/30/14	Vacancies as of 9/30/14	Nominees Received (10/01/13-9/30/14)	Nominees Willing to Serve (10/1/13-9/30/14)
- Orthopedic and Rehabilitation Devices Panel	9	1	3	3	9	1	3	3
- Radiological Devices Panel	9	3	2	0	9	5	0	0
National Mammography Quality Assurance Advisory Committee	19	3	5	2	19	6	4	4
Technical Electronic Product Radiation Safety Standards Committee	15	0	4	3	15	1	0	0
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION	17	1	4	3	17	2	30	18
Food Advisory Committee	17	1	4	3	17	2	30	18
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	9	1	3	4	9	0	9	9
Science Advisory Board to the National Center for Toxicological Research	9	1	3	4	9	0	9	9
CENTER FOR TOBACCO PRODUCTS	12	0	3	3	12	0	34	3
Tobacco Products Scientific Advisory Committee	12	0	3	3	12	0	34	3

*Effective May 31, 2014, Drug Safety and Risk Management decreased authorized membership from 14 to 12.
**Effective February 1, 2014, Pharmaceutical Science and Clinical Pharmacology decreased the total authorized membership by 13 from 30 to 17; 5 vacancies remained from the 18 reported in FY 2013.
***On April 25, 2012, the charter for the Pharmacy Compounding Advisory Committee was filed, re-establishing the Committee. Committee member appointments are under review at the time of this report.
****Effective June 4, 2014, Psychopharmacologic Drugs decreased authorized membership from 12 to 10.
*****Effective March 23, 2014, Reproductive Health Drugs changed the committee name to Bone, Reproductive and Urologic Drugs and decreased authorized membership from 14 to 12.

Section 712(e)(1)(D) of the FD&C Act calls for an annual report of the aggregate number of waiver disclosures required under section 712(c) and the percentage of individuals to whom such disclosures did not apply who served on such committee. Under section 712(c), FDA is required to publicly disclose on its website the type, nature, and magnitude of the financial interests of each advisory committee member who receives a waiver under the federal conflict of interests laws⁵ that apply to all advisory committees, and the reasons for granting the waiver.⁶ This information is posted on FDA's website prior to each meeting. Table 2 presents the number of individuals contacted who did not serve due to potential conflicts of interest and those who did not serve for reasons other than potential conflicts of interest. Table 2 also presents the number of waiver disclosures made in FY 2014 and the percentage of individuals to whom disclosures did not apply in FY 2014.

⁵ 18 U.S.C. 208

⁶ A waiver under 18 USC 208(b)(1) may be granted for an employee if the financial interest is not so substantial as to be deemed likely to affect the integrity of the employee's services. A waiver under 18 USC 208(b)(3) may be granted for a special governmental employee serving on a federal advisory committee if the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved. Under 21 USC 379d-1(c)(1)(B), the reasons for a waiver determination must be disclosed, including, as appropriate, a statement concerning the public health interest in having the expertise of the member with respect to the particular matter before the advisory committee.

Table 2 - 712(e)(1)(D) Number of Meetings, Persons Contacted, Persons Contacted Who Did Not Serve, Participants, and Waivers Granted FY 2014

	Number of Meetings	# of persons contacted (attending and not attending)*	# of persons contacted and not serving due to potential conflicts of interest	# of persons contacted and not serving due to reasons other than potential conflicts of interest	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
FDA TOTAL	74	1963	107	741	1115	3	1112	99.73%

Committee Name	Meeting Date	Number of Meetings	# of persons contacted (attending and not attending)*	# of persons contacted and not serving due to potential conflicts of interest	# of persons contacted and not serving due to reasons other than potential conflicts of interest	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total meeting Participants with no waivers	% of Meeting Participants <u>Not</u> Issued Waivers
OFFICE OF THE COMMISSIONER		6	139	4	27	108	0	108	100.00%
Science Board to the Food and Drug Administration	2/5/14	1	17	0	0	17	0	17	100.00%
Science Board to the Food and Drug Administration	6/4/14	1	22	0	3	19	0	19	100.00%
Pediatric Advisory Committee	4/21/14	1	26	3	8	15	0	15	100.00%
Pediatric Advisory Committee	9/23/14	1	20	1	3	16	0	16	100.00%
Risk Communication (RCAC)	12/17/13	1	31	0	10	21	0	21	100.00%
Risk Communication (RCAC)	5/5-6/2014	1	23	0	3	20	0	20	100.00%
CENTER FOR BIOLOGICS EVALUATION & RESEARCH		10	174	4	33	137	0	137	100.00%
Allergenic Products	12/11-12/13	1	11	0	1	10	0	10	100.00%
Allergenic Products	1/28/2014	1	9	0	0	9	0	9	100.00%
Blood Products	11/1/2013	1	27	1	9	17	0	17	100.00%
Blood Products	3/18-19/14	1	19	0	5	14	0	14	100.00%
Blood Products	7/31/2014	1	24	1	3	20	0	20	100.00%
Cellular, Tissue and Gene Therapies	2/25-26/14	1	28	0	6	22	0	22	100.00%
Cellular, Tissue and Gene Therapies	9/18/14	1	11	0	4	7	0	7	100.00%
Transmissible Spongiform Encephalopathies	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.00%
Vaccines and Related Biological Products	11/13/13	1	12	0	1	11	0	11	100.00%
Vaccines and Related Biological Products	2/28/14	1	20	2	1	17	0	17	100.00%
Vaccines and Related Biological Products	3/20/14	1	13	0	3	10	0	10	100.00%
CENTER FOR DRUG EVALUATION AND RESEARCH		36	1095	59	475	561	2	559	99.64%
Anesthetic and Analgesic Drug Products Advisory Committee	4/22/14	1	29	1	14	14	0	14	100.00%

Committee Name	Meeting Date	Number of Meetings	# of persons contacted (attending and not attending)*	# of persons contacted and not serving due to potential conflicts of interest	# of persons contacted and not serving due reasons other than potential conflicts of interest	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total meeting Participants with no waivers	% of Meeting Participants <u>Not</u> Issued Waivers
Anesthetic and Analgesic Drug Products Advisory Committee	6/11-12/14	1	66	5	37	24	0	24	100.00%
Anti-Infective Drugs Advisory Committee	10/17/13	1	32	1	13	18	0	18	100.00%
Anti-Infective Drugs Advisory Committee	10/18/13	1	20	0	4	16	0	16	100.00%
Anti-Infective Drugs Advisory Committee	3/31/14	1	25	1	10	14	0	14	100.00%
Antiviral Drugs Advisory Committee	10/24/13	1	23	4	0	19	0	19	100.00%
Antiviral Drugs Advisory Committee	10/25/13	1	22	4	3	15	0	15	100.00%
Arthritis Advisory Committee (joint w/ DSaRM)	2/10-11/14	1	49	7	17	25	0	25	100.00%
Bone, Reproductive and Urologic Drugs Advisory Committee (joint w/ DSaRM)	9/17/14	1	56	0	35	21	1	20	95.24%
Bone, Reproductive and Urologic Drugs Advisory Committee (joint w/ DSaRM)	9/18/14	1	55	0	34	21	1	20	95.24%
Cardiovascular and Renal Drugs Advisory Committee	1/14/14	1	22	1	4	17	0	17	100.00%
Cardiovascular and Renal Drugs Advisory Committee	1/15/14	1	18	2	5	11	0	11	100.00%
Cardiovascular and Renal Drugs Advisory Committee	1/16/14	1	18	1	6	11	0	11	100.00%
Cardiovascular and Renal Drugs Advisory Committee	2/12/14	1	15	0	6	9	0	9	100.00%
Cardiovascular and Renal Drugs Advisory Committee	3/27/14	1	17	0	6	11	0	11	100.00%
Cardiovascular and Renal Drugs Advisory Committee	9/9/14	1	20	1	9	10	0	10	100.00%
Cardiovascular and Renal Drugs Advisory Committee	9/10/14	1	21	0	6	15	0	15	100.00%
Dermatologic and Ophthalmic Drugs Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Drug Safety and Risk Management Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Endocrinologic and Metabolic Drugs Advisory Committee	10/16/13	1	27	2	14	11	0	11	100.00%
Endocrinologic and Metabolic Drugs Advisory Committee	11/19/13	1	37	2	14	21	0	21	100.00%
Endocrinologic and Metabolic Drugs Advisory Committee	12/11/13	1	28	1	15	12	0	12	100.00%
Endocrinologic and Metabolic Drugs Advisory Committee	12/12/13	1	44	1	29	14	0	14	100.00%

Endocrinologic and Metabolic Drugs Advisory Committee	4/1/14	1	26	1	10	15	0	15	100.00%
Endocrinologic and Metabolic Drugs Advisory Committee	9/11/14	1	39	4	20	15	0	15	100.00%
Endocrinologic and Metabolic Drugs Advisory Committee	9/12/14	1	24	0	11	13	0	13	100.00%
Gastrointestinal Drugs Advisory Committee (joint w/ Drug Safety and Risk Management Advisory Committee)	12/9/13	1	51	3	26	22	0	22	100.00%
Medical Imaging Drugs Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Nonprescription Drugs Advisory Committee (joint w/ Pulmonary-Allergy Drugs Advisory Committee)	2/25/14	1	30	0	5	25	0	25	100.00%
Nonprescription Drugs Advisory Committee	2/26/14	1	29	0	8	21	0	21	100.00%
Nonprescription Drugs Advisory Committee	5/2/14	1	35	0	20	15	0	15	100.00%
Nonprescription Drugs Advisory Committee	9/3/14	1	29	0	17	12	0	12	100.00%
Nonprescription Drugs Advisory Committee	9/4-5/14	1	34	2	13	19	0	19	100.00%
Oncologic Drugs Advisory Committee (Pediatric Oncology Subcommittee)	11/04/13	1	25	3	12	10	0	10	100.00%
Oncologic Drugs Advisory Committee (Pediatric Oncology Subcommittee)	11/5/13	1	26	3	13	10	0	10	100.00%
Oncologic Drugs Advisory Committee	6/25/14	1	20	2	5	13	0	13	100.00%
Peripheral and Central Nervous System Drugs Advisory Committee	11/13/13	1	36	3	15	18	0	18	100.00%
Peripheral and Central Nervous System Drugs Advisory Committee	11/14/13	1	17	0	6	11	0	11	100.00%
Pharmaceutical Science and Clinical Pharmacology Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pharmacy Compounding Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Psychopharmacologic Drugs Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pulmonary-Allergy Drugs Advisory Committee	8/14/14	1	30	4	13	13	0	13	100.00%
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION		1	15	0	3	12	0	12	100.00%
Food Advisory Committee	9/29-30/2014	1	15	0	3	12	0	12	100.00%
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		19	510	39	192	279	1	278	99.64%
Device Good Manufacturing Practice Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Medical Devices Advisory Committee (Comprised of 18 Panels)									

Committee Name	Meeting Date	Number of Meetings	# of persons contacted (attending and not attending)*	# of persons contacted and not serving due to potential conflicts of interest	# of persons contacted and not serving due reasons other than potential conflicts of interest	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total meeting Participants with no waivers	% of Meeting Participants <u>Not</u> Issued Waivers
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH CONT'									
Anesthesiology and Respiratory Therapy Devices Panel	2/20/14	1	22	2	4	16	0	16	100.00%
Clinical Chemistry and Clinical Toxicology Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Circulatory System Devices Panel	10/8/2-13-10/9/13	1	27	4	6	17	0	17	83.33%
Circulatory System Devices Panel	12/11/13	1	25	4	4	17	0	17	100.00%
Circulatory System Devices Panel	5/6/14 - 5/7/14	1	29	0	10	19	0	19	100.00%
Circulatory System Devices Panel	6/12/14	1	25	5	8	12	0	12	100.00%
Dental Products Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Ear, Nose, and Throat Devices Panel	11/8/13	1	30	3	11	16	0	16	100.00%
Gastroenterology and Urology Devices Panel	3/20/14	1	20	1	6	13	0	13	100.00%
Gastroenterology and Urology Devices Panel	6/17/14	1	28	3	13	12	1	11	91.67%
Gastroenterology and Urology Devices Panel	7/30/14 - 7/31/14	1	31	4	13	14	0	14	100.00%
General and Plastic Surgery Devices Panel	8/1/14	1	19	0	5	14	0	14	100.00%
General Hospital and Personal Use Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Hematology and Pathology Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Immunology Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Medical Devices Dispute Resolution Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Microbiology Devices Panel	3/12/14	1	31	7	7	17	0	17	100.00%
Molecular and Clinical Genetics Devices Panel	3/26/14 - 3/27/14	1	27	3	11	13	0	13	100.00%
Neurological Devices Panel	4/24/14	1	33	0	15	18	0	18	100.00%
Obstetrics and Gynecology Devices Panel	7/10/14 - 7/11/14	1	34	2	14	18	0	18	100.00%
Ophthalmic Devices Panel	3/14/14	1	24	0	11	13	0	13	100.00%
Ophthalmic Devices Panel	5/13/14	1	26	1	10	15	0	15	100.00%
Ophthalmic Devices Panel	6/6/14	1	33	0	22	11	0	11	100.00%
Orthopedic and Rehabilitation Devices Panel	12/12/13	1	27	0	13	14	0	14	100.00%

Committee Name	Meeting Date	Number of Meetings	# of persons contacted (attending and not attending)*	# of persons contacted and not serving due to potential conflicts of interest	# of persons contacted and not serving due reasons other than potential conflicts of interest	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total meeting Participants with no waivers	% of Meeting Participants <u>Not</u> Issued Waivers
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH CONT'									
Orthopedic and Rehabilitation Devices Panel	2/21/14	1	19	0	9	10	0	10	100.00%
Radiological Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
National Mammography Quality Assurance Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Technical Electronic Products Radiation Safety Standards Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH									
Science Advisory Board to the National Center for Toxicological Research	01/29-30/14	1	9	0	2	7	0	7	100.00%
CENTER FOR TOBACCO PRODUCTS									
Tobacco Products Scientific Advisory Committee	04/16-18/14	1	21	1	9	11	0	11	100.00%

* Not including Industry Representatives, Regular FDA Employees, or Guest Speakers

Reducing the Number of Vacancies on Advisory Committees

FDA uses many strategies to help identify as broad a selection of advisory committee candidates as possible and include qualified experts with the fewest potential conflicts of interest.

Under section 712(b)(1)(A), FDA is to 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. FDA is directed to seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities. FDA is also expected to take into account the levels of activity (including the numbers of annual meetings) and the number of vacancies of the advisory committees. The statute lists a number of suggested recruitment activities. With these suggested strategies in mind, the Agency is currently employing the following outreach practices:

- FDASIA section 712(b)(1)(c) recommends that at least every 180 days, FDA request referrals for potential members of advisory committees from a variety of stakeholders, including (i) product developers, patient groups, and disease advocacy organizations; and (ii) relevant (I) professional societies, (II) medical societies, (III) academic organizations, and (IV) governmental organizations. FDA regularly notifies the public about vacancies on advisory committees through *Federal Register* notices approximately four times annually. Many professional societies use these notices to share news of potential vacancies among interested professionals. In FY 2014, FDA issued 10 of these notices. FDA also uses its Advisory Committee website at <http://www.fda.gov/AdvisoryCommittees/default.htm> to display such vacancies.

- FDA’s advisory committee staff participates in FDA TRACK, an Agency-wide performance plan that provides monthly reporting on measurable objectives on its public website. As part of that effort, the advisory committee program reports on the monthly vacancy rates by committee as well as on Agency outreach activities.
- A staff member in FDA’s Advisory Committee Oversight and Management Staff (ACOMS), Office of the Commissioner, serves as the liaison and point of contact for information regarding the Agency’s advisory committee recruitment activities, vacancies, and nominations. The liaison contacts local, state, and federal authorities, organizations, and universities to discuss strategies for effective outreach and recruitment within those settings.
- Effective January 15, 2014, individuals may submit their *curriculum vitae* and nomination information directly to FDA’s Web Portal Application System. During FY 2014, FDA received more than 500 submissions through the portal.
- Current and retiring committee members, familiar with conflict of interest rules and regulations, are encouraged to communicate with colleagues and recruit new members.
- FDA utilizes new member advisory committee training and updates to encourage current members to recruit and nominate potential candidates.
- FDA actively seeks nominees for consumer representative membership by meeting quarterly with a group of consumer-oriented organizations.
- FDA distributes brochures containing advisory committee information and criteria for membership at training sessions, public advisory committee meetings, and professional scientific meetings. During this reporting period, FDA representatives presented and or distributed recruitment brochures at the following professional meetings:
 1. American Association of Tissue Banks Annual Meeting; National Harbor, Maryland.
 2. Washington Bio-Leaders Forum, Washington, DC.
 3. Science Leaders talk at Howard University, Washington, DC.
 4. The 17th US-Japan Cellular and Gene Therapy Conference, Chimeric Antigen Receptor T Cells for Cancer Therapy, National Institutes of Health, Bethesda, Maryland.
 5. Maryland Public Health Association 2014 Annual Conference, Baltimore, Maryland.
 6. Scoliosis Research Society 49th Annual Meeting, Anchorage, Alaska.
 7. American Association for Cancer Research (AACR), San Diego, California.
 8. National Hispanic Medical Association, Washington, DC.
 9. American Association of Medical Colleges, Philadelphia, Pennsylvania.
 10. American Public Health Association Meeting, Boston, Massachusetts.
 11. American Association of Pharmacists, Washington, DC.
 12. American Association of Family and Consumer Sciences, St. Louis, Missouri.
 13. Gay, Lesbian Medical Association, Baltimore, Maryland.