

Report to Congress

Fiscal Year 2023's Advisory Committee Vacancies and Public Disclosures

Required by the Food and Drug Administration
Safety and Innovation Act



**U.S. FOOD & DRUG
ADMINISTRATION**

Executive Summary

Under section 1142 of the Food and Drug Administration Safety and Innovation Act (FDASIA) enacted in 2012, which amended section 712(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA) is required to provide, on an annual basis, information on its advisory committee vacancies and public disclosures of information about potential advisory committee conflicts of interest. This reporting information was first mandated by the Food and Drug Administration Amendments Act of 2007, which added section 712 to the FD&C Act. This section of the FD&C Act was subsequently modified by FDASIA, as described above.

As required in FDASIA, this report describes the following information for fiscal year (FY) 2023:

- 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 2023 include:

- FDA granted 23 waivers under 18 U.S.C. 208(b)(3) in FY 2023 (less than 3 percent of total meeting participants in attendance at meetings), which is a slight increase from the 22 waivers granted in FY 2022 (see Figure 2).
- Five 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 FDA.

- FDA received 234 applications for available positions on advisory committees and panels during FY 2023. FDA identified 169 of the nominees (72 percent) as being qualified and willing to serve.

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I. Background

Section 712(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379d-1(e))¹ requires the Food and Drug Administration (FDA or Agency) to report annually on its advisory committee vacancies and public disclosures of information. Specifically, section 712(e)(1)² requires a report, “[n]ot later than February 1 of each year,” “that describes” the following:

- 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.

This report covers the period from October 1, 2022, through September 30, 2023.

¹ 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, which was effective on October 1, 2012. Title VII of FDAAA added new conflict of interest provisions, effective October 1, 2007, applicable to FDA’s advisory committees.

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

II. Scope of the FY 2023 Annual Report

In response to the information to be reported under section 712(e)(1)(A), Table 1 presents, for fiscal year (FY) 2023, data on the number of vacancies on each advisory committee, the number of nominations received³ for such vacancies, and the number of such nominees willing to serve⁴ on for each advisory committee.

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. 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 end of FY 2022, the number of new vacancies that occurred during FY 2023, the number of these vacancies filled during FY 2023, the number of nominees received to fill those new vacancies, and of those received and reviewed during FY 2023, the number of nominees willing to serve.

The number of vacancies on FDA's advisory committees increased from 14 percent in FY 2022 to 21 percent in FY 2023 (see Figure 1).

³ FDA considers a nomination "received" when the submission includes all of the following information for the nominee: complete *curriculum vitae* (CV), 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. Beginning June 28, 2017, a signed consent form allowing disclosure of the CV if the nominee is selected is also required. See 82 FR 23583 (May 23, 2017), available at <https://www.federalregister.gov/documents/2017/05/23/2017-10531/agency-information-collection-activities-submission-for-office-of-management-and-budget-review>.

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.

Table 1 – FY 2023’s Pre-existing Vacancies, New Vacancies, Nominees Received, and Nominees Willing to Serve

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/22	Vacancies as of 9/30/22	New Vacancies During Reporting Period (10/01/22 - 9/30/23)	Vacancies Filled (10/01/22 - 9/30/23)	Authorized Membership as of 9/30/23	Vacancies as of 9/30/23	Nominees Received (10/01/22 - 9/30/23)	Nominees Willing to Serve (10/1/22 - 9/30/23)
Total of All Offices/Centers	532	77	132	97	532	112	234	169
Office of the Commissioner	37	8	14	12	37	10	33	15
Pediatric Advisory Committee	16	0	4	3	16	1	8	6
Science Board to the Food and Drug Administration	21	8	10	9	21	9	25	9
Center for Biologics Evaluation and Research	58	4	14	10	58	8	16	12
Allergenic Products Advisory Committee	10	3	3	0	10	6	3	0
Blood Products Advisory Committee	18	1	4	5	18	0	3	7
Cellular, Tissue, & Gene Therapies Advisory Committee	14	0	4	2	14	2	7	2
Vaccines and Related Biological Products Advisory Committee	16	0	3	3	16	0	3	3

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/22	Vacancies as of 9/30/22	New Vacancies During Reporting Period (10/01/22 - 9/30/23)	Vacancies Filled (10/01/22 - 9/30/23)	Authorized Membership as of 9/30/23	Vacancies as of 9/30/23	Nominees Received (10/01/22 - 9/30/23)	Nominees Willing to Serve (10/1/22 - 9/30/23)
Center for Drug Evaluation and Research	209	6	51	26	209	32	91	90
Anesthetic and Analgesic Drug Products Advisory Committee	12	0	3	2	12	1	2	2
Antimicrobial Drugs Advisory Committee	14	0	4	3	14	1	9	8
Arthritis Advisory Committee	12	0	2	2	12	1	0	0
Cardiovascular and Renal Drugs Advisory Committee	12	0	3	2	12	1	10	10
Dermatologic and Ophthalmic Drugs Advisory Committee	10	0	3	0	10	3	3	3
Drug Safety and Risk Management Advisory Committee	12	0	1	1	12	0	13	13
Endocrinologic and Metabolic Drugs Advisory Committee	12	1	4	0	12	5	7	7
Gastrointestinal Drugs Advisory Committee	12	0	4	0	12	4	2	2

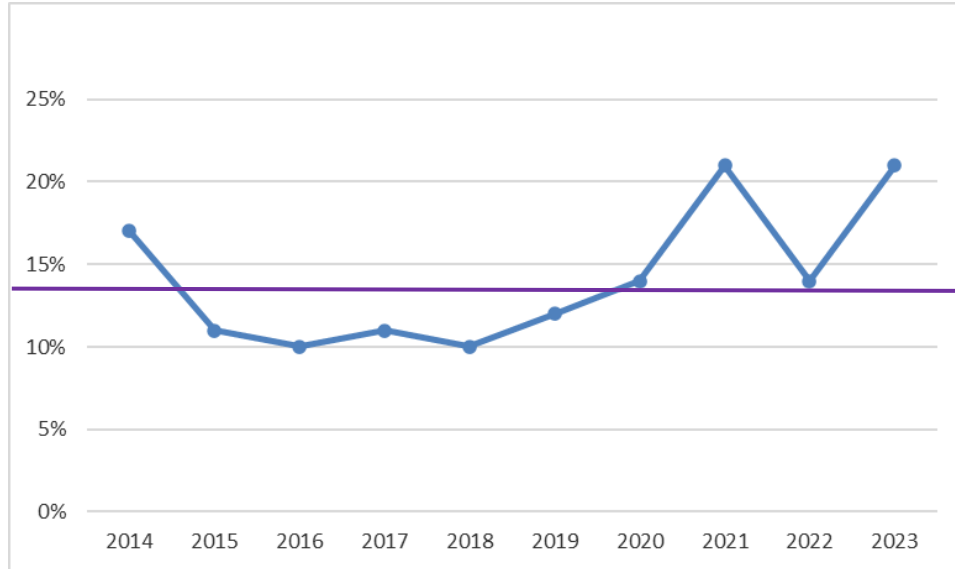
Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/22	Vacancies as of 9/30/22	New Vacancies During Reporting Period (10/01/22 - 9/30/23)	Vacancies Filled (10/01/22 - 9/30/23)	Authorized Membership as of 9/30/23	Vacancies as of 9/30/23	Nominees Received (10/01/22 - 9/30/23)	Nominees Willing to Serve (10/1/22 - 9/30/23)
Medical Imaging Drugs Advisory Committee	13	1	4	0	13	5	2	2
Nonprescription Drugs Advisory Committee	11	1	1	1	11	1	6	6
Obstetrics, Reproductive and Urologic Drugs Advisory Committee	12	0	2	0	12	2	4	4
Oncologic Drugs Advisory Committee	14	0	3	3	14	0	9	9
Peripheral and Central Nervous System Drugs Advisory Committee	10	1	3	1	10	3	6	6
Pharmaceutical Science and Clinical Pharmacology Advisory Committee	17	2	5	4	17	3	8	8
Pharmacy Compounding Advisory Committee	14	0	4	3	14	1	5	5
Psychopharmacologic Drugs Advisory Committee	10	0	0	0	10	0	3	3
Pulmonary-Allergy Drugs Advisory Committee	12	0	5	4	12	1	2	2

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/22	Vacancies as of 9/30/22	New Vacancies During Reporting Period (10/01/22 - 9/30/23)	Vacancies Filled (10/01/22 - 9/30/23)	Authorized Membership as of 9/30/23	Vacancies as of 9/30/23	Nominees Received (10/01/22 - 9/30/23)	Nominees Willing to Serve (10/1/22 - 9/30/23)
Center for Devices and Radiological Health	207	56	47	42	207	61	104	45
Device Good Manufacturing Practice Advisory Committee	9	0	1	0	9	1	2	0
National Mammography Quality Assurance Advisory Committee	15	2	4	4	15	2	3	2
Patient Engagement Advisory Committee	9	0	3	3	9	0	18	3
Technical Electronic Product Radiation Safety Standards Committee	15	6	4	0	15	10	2	13
Medical Devices Advisory Committee (Composed of 18 Panels)								
Anesthesiology and Respiratory Therapy Devices Panel	9	3	2	4	9	1	2	0
Circulatory System Devices Panel	9	2	3	4	9	1	4	2
Clinical Chemistry and Clinical Toxicology Devices Panel	9	3	1	1	9	3	1	0

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/22	Vacancies as of 9/30/22	New Vacancies During Reporting Period (10/01/22 - 9/30/23)	Vacancies Filled (10/01/22 - 9/30/23)	Authorized Membership as of 9/30/23	Vacancies as of 9/30/23	Nominees Received (10/01/22 - 9/30/23)	Nominees Willing to Serve (10/1/22 - 9/30/23)
Dental Products Panel	10	6	2	0	10	8	21	9
Ear, Nose, and Throat Devices Panel	9	4	3	0	9	7	3	0
Gastroenterology- Urology Devices Panel	9	1	2	3	9	0	1	0
General and Plastic Surgery Devices Panel	9	0	3	0	9	3	3	0
General Hospital and Personal Use Devices Panel	9	2	4	1	9	5	0	0
Hematology and Pathology Devices Panel	9	5	3	3	9	5	3	3
Immunology Devices Panel	9	0	1	1	9	0	1	0
Medical Devices Dispute Resolution Panel	5	0	1	1	5	0	0	0
Microbiology Devices Panel	9	2	0	1	9	1	0	0
Molecular and Clinical Genetics Panel	9	5	4	4	9	5	3	3

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/22	Vacancies as of 9/30/22	New Vacancies During Reporting Period (10/01/22 - 9/30/23)	Vacancies Filled (10/01/22 - 9/30/23)	Authorized Membership as of 9/30/23	Vacancies as of 9/30/23	Nominees Received (10/01/22 - 9/30/23)	Nominees Willing to Serve (10/1/22 - 9/30/23)
Neurological Devices Panel	9	2	1	0	9	3	0	0
Obstetrics and Gynecology Devices Panel	9	5	0	4	9	1	9	1
Ophthalmic Devices Panel	9	1	1	1	9	1	3	1
Orthopedic and Rehabilitation Devices Panel	9	5	2	5	9	2	22	7
Radiological Devices Panel	9	2	2	2	9	2	1	1
National Center for Toxicological Research	9	2	4	5	9	1	3	5
Science Advisory Board to the National Center for Toxicological Research	9	2	4	5	9	1	3	5
Center for Tobacco Products	12	0	2	2	12	0	18	2
Tobacco Products Scientific Advisory Committee	12	0	2	2	12	0	18	2

Figure 1 – Percentage of Advisory Committee Vacancies



Section 712(e)(1)(D) calls for an annual report of the aggregate number of waiver disclosures required under section 712(c)⁵ 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 conflicts of interest law⁶ that applies to all advisory committees, as well as the reasons for granting that waiver.⁷ This information is posted on FDA’s website prior to each meeting.

Table 2 presents the number of individuals contacted who did not serve in each advisory committee meeting 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 2023 and the percentage of individuals to whom disclosures did not apply in that fiscal year.

⁵ Section 712(e)(1)(D) requires that FDA report “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.” Subsection (d) does not require disclosures, but instead requires that disclosures required under subsection (c) be included in the public record and transcript of the advisory committee meeting. FDA therefore reads the citation in 712(e)(1)(D) to be referring to disclosures required under subsection (c).

⁶ 18 U.S.C. 208.

⁷ A waiver under 18 U.S.C. 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 U.S.C. 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.

Table 2 – FY 2023’s Section 712(e)(1)(D) Number of Meetings, Persons Contacted, Persons Contacted Who Did Not Serve, Participants, and Waivers Granted

Committee Name	Meeting Date	# 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 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
FDA’s TOTALS	-----	53	1340	73	441	826	23	803	97.22%
Office of the Commissioner		1	13	1	0	12	0	12	100.00%
Science Board to the Food and Drug Administration	12/8/2022	1	12	0	0	12	0	12	100.00%
Pediatric Advisory Committee	9/19/2023	1	33	0	7	26	0	26	100.00%
Center for Biologics Evaluation and Research		10	242	27	54	161	3	158	98.14%
Cellular, Tissue, and Gene Therapies Advisory Committee	5/12/2023	1	32	6	11	15	0	15	100.00%
Cellular, Tissue, and Gene Therapies Advisory Committee	9/27/2023	1	48	6	22	20	1	19	95.00%

Committee Name	Meeting Date	# 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 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants Not Issued Waivers
Blood Products	12/8/2022	1	18	0	3	15	0	15	100.00%
Blood Products	4/26/2023	1	18	0	3	15	0	15	100.00%
Vaccines and Related Biological Products	10/6/2022	1	17	1	1	15	0	15	100.00%
Vaccines and Related Biological Products	1/26/2023	1	25	4	3	18	1	17	94.44%
Vaccines and Related Biological Products	2/28-3/1/2023	1	20	2	4	14	0	14	100.00%
Vaccines and Related Biological Products	3/7/2023	1	15	0	3	12	0	12	100.00%
Vaccines and Related Biological Products	5/18/2023	1	22	4	3	15	0	15	100.00%
Vaccines and Related Biological Products	6/15/2023	1	27	4	1	22	1	21	95.45%
Vaccines and Related Biological Products	1/26/2023	1	25	4	3	18	1	17	94.44%
Center for Drug Evaluation and Research		31	748	24	244	480	11	469	97.71

Committee Name	Meeting Date	# 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 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants Not Issued Waivers
Anesthetic and Analgesic Drug Products Advisory Committee	4/19/2023	1	16	0	3	13	0	13	100.00%
Obstetrics, Reproductive, and Urologic Drugs Advisory Committee	10/17-19/2022	1	34	0	18	16	0	16	100.00%
Anesthetic and Analgesic Drug Products Advisory Committee	4/19/2023	1	16	0	3	13	0	13	100.00%
Obstetrics, Reproductive, and Urologic Drugs Advisory Committee	10/17-19/2022	1	34	0	18	16	0	16	100.00%
Antimicrobial Drugs Advisory Committee	4/17/2023	1	14	0	1	13	0	13	100.00%
Antimicrobial Drugs Advisory Committee	3/16/2023	1	24	2	4	18	2	16	88.89%
Antimicrobial Drugs Advisory Committee	6/8/2023	1	26	0	4	22	2	20	90.91%

Committee Name	Meeting Date	# 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 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
Antimicrobial Drugs Advisory Committee	1/24/2023	1	19	1	2	16	0	16	100.00%
Cardiovascular and Renal Drugs Advisory Committee	10/26/2022	1	27	1	9	17	0	17	100.00%
Cardiovascular and Renal Drugs Advisory Committee	11/16/2022	1	18	1	3	14	0	14	100.00%
Cardiovascular and Renal Drugs Advisory Committee	12/13/2022	1	17	0	5	12	0	12	100.00%
Cardiovascular and Renal Drugs Advisory Committee	9/13/2023	1	17	0	4	13	0	13	100.00%
Dermatologic and Ophthalmic Drugs Advisory Committee	1/9/2023	1	15	2	5	8	0	8	100.00%
Endocrinologic and Metabolic Drugs Advisory Committee	6/28/2023	1	22	0	7	15	0	15	100.00%
Endocrinologic and Metabolic Drugs Advisory Committee	9/21/2023	1	32	1	11	20	0	20	100.00%

Committee Name	Meeting Date	# 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 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
Gastrointestinal Drugs Advisory Committee	5/19/2023	1	25	1	7	17	3	14	82.35%
Joint meeting- Drug Safety and Risk Management Advisory Committee and the Ophthalmic Drugs Advisory Committee	3/28-29/2023	1	38	0	15	23	0	23	100.00%
Joint Meeting- Nonprescription Drugs Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee	2/15/2023	1	28	1	6	21	0	21	100.00%
Joint Meeting- Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee	5/9-10/2023	1	28	0	9	19	0	19	100.00%

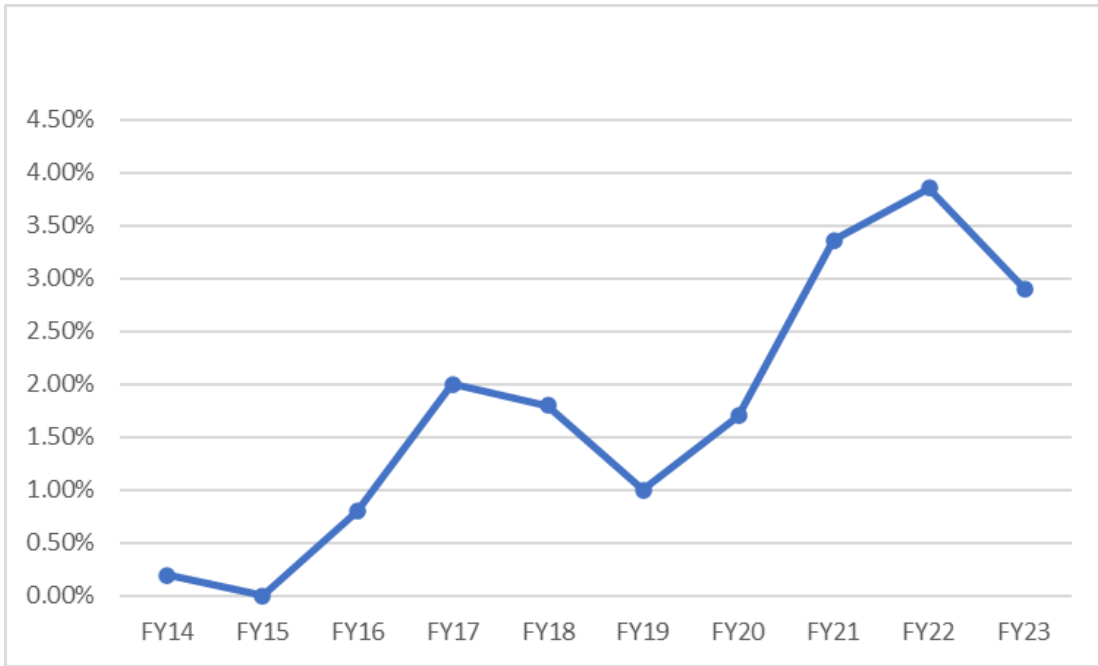
Committee Name	Meeting Date	# of Meetings	# of Persons Contacted (Attending and Not Attending)*	# of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	# of Persons Contacted and Not Serving Due to Reasons Other Than Potential Conflicts of Interest	Total Number of Meeting Participants Attending (Voting & Nonvoting)*	18 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
Joint Meeting- Psychopharmacologic Drugs Advisory Committee and the Peripheral and Central Nervous System Drugs Advisory Committee	4/14/2023	1	18	2	5	11	1	10	90.91%
Medical Imaging Drugs Advisory Committee	8/1/2023	1	16	0	1	15	0	15	100.00%
Nonprescription Drugs Advisory Committee	9/11-12/2023	1	38	0	21	17	0	17	100.00%
Oncologic Drugs Advisory Committee	10/28/2022	1	38	1	20	17	0	17	100.00%
Oncologic Drugs Advisory Committee	2/9/2023	1	22	0	8	14	1	13	92.86%
Oncologic Drugs Advisory Committee	3/9/2023	1	28	0	14	14	0	14	100.00%
Oncologic Drugs Advisory Committee	4/28/2023	1	27	1	12	14	0	14	100.00%

Committee Name	Meeting Date	# 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 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants Not Issued Waivers
Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee	6/16/2023	1	17	0	3	14	0	14	100.00%
Peripheral and Central Nervous System Drugs Advisory Committee	3/22/2023	1	15	1	4	10	1	9	90.00%
Peripheral and Central Nervous System Drugs Advisory Committee	6/9/2023	1	18	3	8	7	1	6	85.71%
Pharmaceutical Science and Clinical Pharmacology Advisory Committee	11/2-3/2022	1	21	1	4	17	0	17	100.00%
Pulmonary-Allergy Drugs Advisory Committee	11/8/2022	1	31	2	12	18	0	18	100.00%
Pulmonary-Allergy Drugs Advisory Committee	11/9/2022	1	23	2	7	14	0	14	100.00%
Pulmonary-Allergy Drugs Advisory Committee	5/11/2023	1	36	1	12	23	0	23	100.00%

Committee Name	Meeting Date	# 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 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants Not Issued Waivers
Center for Devices and Radiological Health		8	287	22	136	129	9	120	93.02%
Anesthesiology Devices Panel	11/1/2022	1	29	0	12	17	1	16	94.12%
Circulatory System Devices Panel	8/22-23/2023	1	41	14	10	17	4	13	76.47%
Clinical Chemistry and Clinical Toxicology Devices Panel	10/20/2022	1	40	2	22	16	0	16	100.00%
General and Plastic Surgery Devices Panel	10/26-27/2023	1	62	2	35	25	1	24	96.00%
Microbiology Devices Panel	9/7-8/2023	1	39	3	20	16	1	15	93.75%
Ophthalmic Devices Panel	11/10/2022	1	18	1	5	12	0	12	100.00%
Orthopedic and Rehabilitation Devices Panel	4/20/2023	1	42	0	30	12	0	12	100.00%
Patient Engagement Advisory Committee	9/6/2023	1	16	0	2	14	2	12	85.71%

Committee Name	Meeting Date	# 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 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants Not Issued Waivers
National Center for Toxicological Research		1	9	0	0	9	0	9	100.00%
Science Advisory Board to the National Center for Toxicological Research	4/4-5/2023	1	9	0	0	9	0	9	100.00%
Center for Tobacco Products		1	9	0	0	9	0	9	100.00%
Tobacco Products Scientific Advisory Committee	5/18/2023	1	9	0	0	9	0	9	100.00%

Figure 2 – 18 U.S.C. 208 Waivers Granted by Fiscal Year



III. 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 consider the levels of activity (including the numbers of annual meetings) and the numbers of vacancies on 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:

- Section 712(b)(1)(c) of the FD&C Act requires 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 the *Federal Register*. Many professional societies use these notices to share news of potential vacancies among interested professionals. In FY 2023, FDA issued 12 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 participate in FDA-TRACK, an Agency-wide performance plan that provides, on FDA's public website, monthly reporting on measurable objectives. As part of that effort, the Advisory Committee Oversight and Management Staff (ACOMS), which is in the Office of the Commissioner, serves as the liaison and point of contact for information regarding the Agency's advisory committees. ACOMS reports not only on the monthly vacancy rates by committee but also the number of advisory committee meetings held per month.
- A staff member in ACOMS conducts functions related to recruitment activities, vacancies, and nominations of the Agency's advisory committees. This staff member contacts groups—such as local, state, and federal authorities, organizations, and universities—to discuss strategies for effective outreach and recruitment within those settings.

- Current and retiring committee members, familiar with conflict-of-interest rules and regulations, are encouraged to discuss these requirements with colleagues and recruit new members.
- FDA utilizes new member advisory committee trainings and updates to encourage current members to recruit and nominate potential candidates.
- FDA actively seeks nominees for consumer representative membership by engaging with consumer-oriented organizations. These efforts were performed remotely during FY 2023 via mass e-mail.
- FDA representatives met with relevant organizations to explain the advisory committee program and the process for nominating candidates.
- FDA traditionally 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 distributed brochures at public advisory committee meetings.
- During FY 2023, FDA disseminated recruitment information to expert scientists and public health specialists with as many as three mass e-mailings each month.
- During FY 2023, FDA issued 12 *Federal Register* notices announcing a request for nominations to various Agency advisory committees.
- FDA presented brochures to the American Public Health Association, National Medical Association, and National Hispanic Association to recruit advisory committee members.

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This report is available on FDA's home page at <https://www.fda.gov/>.

