

# Report to Congress

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## Fiscal Year 2021's Advisory Committee Vacancies and Public Disclosures

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(Required by the Food and Drug Administration Safety and  
Innovation Act)



## Executive Summary

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

As required in FDASIA, this report describes the following information for fiscal year (FY) 2021:

- 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 at each advisory committee meeting for each advisory committee;
- The number of persons contacted for service as members at 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 at 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 FDA in FY 2021 include the following:

- FDA increased the number of waivers granted under 18 U.S.C. 208(b)(3), from 9 waivers in FY 2020 to 26 waivers for FY 2021, which is still less than four percent of total meeting participants for the year. This increase was largely driven by three meetings for which limited expertise was available; therefore, 14 waivers were granted. Additionally, one member of the Vaccines and Related Biological Products Advisory Committee required a waiver for each of six different meetings at which COVID-19 vaccines/treatments were discussed.
- 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 289 applications from the Membership Nomination Portal. FDA identified 90 of the nominees (31 percent) as being qualified and willing to serve.

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## Background

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Section 712(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379d-1(e))<sup>1</sup> 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)<sup>2</sup> 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.*

## Reporting Period

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This report covers the period from October 1, 2020, through September 30, 2021.

## Scope of This Report

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In response to the information to be reported under section 712(e)(1)(A), Table 1 presents, for fiscal year (FY) 2021, data on the number of vacancies on each advisory committee, the number of nominations received<sup>3</sup> for such vacancies, and the number of

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<sup>1</sup> 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.

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

<sup>3</sup> FDA considers a nomination “received” when the submission includes all on the following information for the nominee: complete *curriculum vitae* (CV), a current address and telephone number, the advisory

nominees willing to serve<sup>4</sup> on each advisory committee.

The number of vacancies on an FDA advisory committee may vary within any given fiscal 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 2020; the number of new vacancies that occurred during FY 2021; the number of these new vacancies filled during FY 2021; the number of nominees received to fill those new vacancies; and of those received and reviewed during FY 2021, the number of nominees willing to serve.

The number of vacancies on FDA's advisory committees increased from 14 percent in FY 2020 to 21 percent in FY 2021 (see Figure 1).

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committee(s) or advisory panel(s) for which the nominee is recommended, and a written confirmation that the nominee is aware of the nomination. In addition, 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 (notice of FDA's information collection covering the advisory committee nomination process).

<sup>4</sup> See section 712(e)(1)(A) 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's requirements for service, including conflict of interest requirements.

**Table 1 - FY 2021's Pre-existing Vacancies, New Vacancies, Nominees Received, and Nominees Willing to Serve**

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/20	Vacancies as of 9/30/20	New Vacancies During Reporting Period (10/01/20 - 9/30/21)	Vacancies Filled (10/01/20 - 9/30/21)	Authorized Membership as of 9/30/21	Vacancies as of 9/30/21	Nominees Received (10/01/20 - 9/30/21)	Nominees Willing to Serve (10/1/20- 9/30/21)
<b>Total of All Offices/Centers</b>	<b>532</b>	<b>70</b>	<b>152</b>	<b>109</b>	<b>532</b>	<b>113</b>	<b>289</b>	<b>90</b>
<b>Center for Biologics Evaluation &amp; Research</b>	<b>58</b>	<b>2</b>	<b>11</b>	<b>8</b>	<b>58</b>	<b>5</b>	<b>31</b>	<b>10</b>
Allergenic Products Advisory Committee	10	1	1	2	10	0	2	1
Blood Products Advisory Committee	18	1	3	3	18	1	9	8
Cellular, Tissue, & Gene Therapies Advisory Committee	14	0	4	2	14	2	5	1
Vaccines and Related Biological Products Advisory Committee	16	0	3	1	16	2	15	0
<b>Center for Devices &amp; Radiological Health</b>	<b>207</b>	<b>50</b>	<b>65</b>	<b>30</b>	<b>207</b>	<b>85</b>	<b>113</b>	<b>31</b>
Device Good Manufacturing Practice Advisory Committee	9	4	4	0	9	8	7	3
National Mammography Quality Assurance Advisory Committee	15	2	5	0	15	7	15	4
Patient Engagement Advisory Committee	9	0	3	2	9	1	25	4

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/20	Vacancies as of 9/30/20	New Vacancies During Reporting Period (10/01/20 - 9/30/21)	Vacancies Filled (10/01/20 - 9/30/21)	Authorized Membership as of 9/30/21	Vacancies as of 9/30/21	Nominees Received (10/01/20 - 9/30/21)	Nominees Willing to Serve (10/1/20- 9/30/21)
Technical Electronic Product Radiation Safety Standards Committee	15	10	5	6	15	9	4	1
<b>Medical Devices Advisory Committee</b>								
Anesthesiology and Respiratory Therapy Devices Panel	9	2	0	0	9	2	1	0
Circulatory System Devices Panel	9	1	1	0	9	2	8	4
Clinical Chemistry and Clinical Toxicology Devices Panel	9	3	4	6	9	1	4	2
Dental Products Panel	10	3	1	0	10	4	1	0
Ear, Nose, and Throat Devices Panel	9	0	4	1	9	3	2	1
Gastroenterology-Urology Devices Panel	9	3	4	6	9	1	1	0
General and Plastic Surgery Devices Panel	9	1	3	0	9	4	7	0
General Hospital and Personal Use Devices Panel	9	1	2	0	9	3	2	1
Hematology and Pathology Devices Panel	9	0	4	0	9	4	0	0

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/20	Vacancies as of 9/30/20	New Vacancies During Reporting Period (10/01/20 - 9/30/21)	Vacancies Filled (10/01/20 - 9/30/21)	Authorized Membership as of 9/30/21	Vacancies as of 9/30/21	Nominees Received (10/01/20 - 9/30/21)	Nominees Willing to Serve (10/1/20- 9/30/21)
Immunology Devices Panel	9	6	2	0	9	8	0	0
Medical Devices Dispute Resolution Panel	5	1	2	3	5	0	8	1
Microbiology Devices Panel	9	3	4	0	9	7	1	0
Molecular and Clinical Genetics Panel	9	1	3	0	9	4	1	0
Neurological Devices Panel	9	3	3	5	9	1	6	3
Obstetrics and Gynecology Devices Panel	9	2	3	0	9	5	4	1
Ophthalmic Devices Panel	9	3	2	1	9	4	2	0
Orthopedic and Rehabilitation Devices Panel	9	0	3	0	9	3	3	1
Radiological Devices Panel	9	1	3	0	9	4	11	5
<b>Center for Drug Evaluation &amp; Research</b>	<b>209</b>	<b>12</b>	<b>62</b>	<b>59</b>	<b>209</b>	<b>15</b>	<b>103</b>	<b>47</b>
Anesthetic and Analgesic Drug Products Advisory Committee	12	1	3	4	12	0	3	4

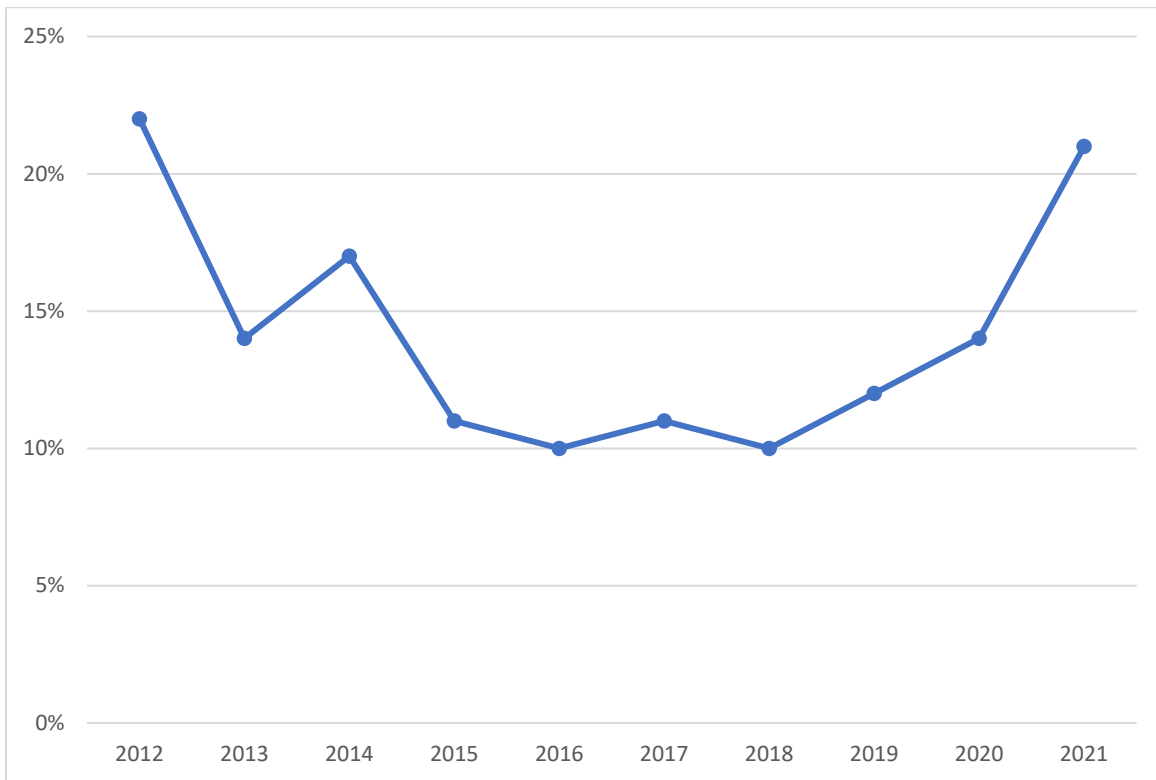


Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/20	Vacancies as of 9/30/20	New Vacancies During Reporting Period (10/01/20 - 9/30/21)	Vacancies Filled (10/01/20 - 9/30/21)	Authorized Membership as of 9/30/21	Vacancies as of 9/30/21	Nominees Received (10/01/20 - 9/30/21)	Nominees Willing to Serve (10/1/20- 9/30/21)
Antimicrobial Drugs Advisory Committee	14	0	3	3	14	0	5	1
Arthritis Advisory Committee	12	0	3	3	12	0	2	4
Bone, Reproductive and Urologic Drugs Advisory Committee	12	4	4	4	12	4	4	2
Cardiovascular and Renal Drugs Advisory Committee	12	0	4	4	12	0	6	2
Dermatologic and Ophthalmic Drugs Advisory Committee	10	0	3	3	10	0	4	3
Drug Safety and Risk Management Advisory Committee	12	1	4	5	12	0	17	9
Endocrinologic and Metabolic Drugs Advisory Committee	12	0	2	2	12	0	4	1
Gastrointestinal Drugs Advisory Committee	12	1	4	4	12	1	8	3
Medical Imaging Drugs Advisory Committee	13	0	6	5	13	1	4	3
Nonprescription Drugs Advisory Committee	11	0	2	2	11	0	5	1
Oncologic Drugs Advisory Committee	14	4	3	7	14	0	7	5

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/20	Vacancies as of 9/30/20	New Vacancies During Reporting Period (10/01/20 - 9/30/21)	Vacancies Filled (10/01/20 - 9/30/21)	Authorized Membership as of 9/30/21	Vacancies as of 9/30/21	Nominees Received (10/01/20 - 9/30/21)	Nominees Willing to Serve (10/1/20- 9/30/21)
Peripheral and Central Nervous System Drugs Advisory Committee	10	0	5	1	10	4	5	2
Pharmaceutical Science and Clinical Pharmacology Advisory Committee	17	0	4	0	17	4	17	2
Pharmacy Compounding Advisory Committee	14	1	5	6	14	0	1	3
Psychopharmacologic Drugs Advisory Committee	10	0	4	4	10	0	9	1
Pulmonary-Allergy Drugs Advisory Committee	12	0	3	2	12	1	2	1
<b>Center for Tobacco Products</b>	<b>12</b>	<b>0</b>	<b>4</b>	<b>4</b>	<b>12</b>	<b>0</b>	<b>10</b>	<b>2</b>
Tobacco Products Scientific Advisory Committee	12	0	4	4	12	0	10	2
<b>National Center for Toxicological Research</b>	<b>9</b>	<b>0</b>	<b>3</b>	<b>2</b>	<b>9</b>	<b>1</b>	<b>4</b>	<b>0</b>
Science Advisory Board to the National Center for Toxicological Research	9	0	3	2	9	1	4	0
<b>Office of the Commissioner</b>	<b>37</b>	<b>6</b>	<b>7</b>	<b>6</b>	<b>37</b>	<b>7</b>	<b>28</b>	<b>0</b>
Pediatric Advisory Committee	16	1	5	6	16	0	7	0

<b>Advisory Committee Name (by Office/Center)</b>	<b>Authorized Membership as of 9/30/20</b>	<b>Vacancies as of 9/30/20</b>	<b>New Vacancies During Reporting Period (10/01/20 - 9/30/21)</b>	<b>Vacancies Filled (10/01/20 - 9/30/21)</b>	<b>Authorized Membership as of 9/30/21</b>	<b>Vacancies as of 9/30/21</b>	<b>Nominees Received (10/01/20 - 9/30/21)</b>	<b>Nominees Willing to Serve (10/1/20- 9/30/21)</b>
Science Board to the Food and Drug Administration	21	5	2	0	21	7	21	0

**Figure 1 – Percent 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)<sup>5</sup> and the percentage of individuals to whom such disclosures did not apply that participated in each advisory committee meeting. 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 law<sup>6</sup> that applies to all advisory committees, as well as the reasons for granting that waiver.<sup>7</sup> This information is posted on FDA’s website prior to each meeting.

Table 2 presents the number of individuals contacted who did not participate in each advisory committee meeting due to potential conflicts of interest and those who did not participate for reasons other than potential conflicts of interest. Table 2 also presents the

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<sup>5</sup> 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).

<sup>6</sup> 18 U.S.C. 208.

<sup>7</sup> 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.

number of waiver disclosures made in FY 2021 and the percentage of individuals to whom disclosures did not apply that fiscal year.

**Table 2 – FY 2021’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 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
<b>FDA’s Totals</b>	-----	<b>37</b>	<b>336</b>	<b>61</b>	<b>121</b>	<b>654</b>	<b>26</b>	<b>632</b>	<b>96.64%</b>
<b>Center for Biologics Evaluation &amp; Research</b>		<b>11</b>	<b>270</b>	<b>18</b>	<b>34</b>	<b>218</b>	<b>11</b>	<b>207</b>	<b>94.95%</b>
Cellular, Tissue and Gene Therapies Advisory Committee	4/15/2021	1	19	1	2	16	0	16	100.00%
Cellular, Tissue and Gene Therapies Advisory Committee	9/2-3/2021	1	25	2	1	22	4	18	81.82%
Vaccines and Related Biological Products Advisory Committee	10/2/2020	1	15	0	0	15	0	15	100.00%
Vaccines and Related Biological Products Advisory Committee	10/22/2020	1	29	6	1	22	2	20	90.91%
Vaccines and Related Biological Products Advisory Committee	12/10/2020	1	35	0	8	27	1	26	96.30%
Vaccines and Related Biological Products Advisory Committee	12/17/2020	1	34	0	7	27	1	26	96.30%
Vaccines and Related Biological Products Advisory Committee	2/26/2021	1	27	0	7	20	1	19	95.00%
Vaccines and Related Biological Products Advisory Committee	3/5/2021	1	16	0	0	16	0	16	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 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
Vaccines and Related Biological Products Advisory Committee	6/10/2021	1	26	0	6	20	1	19	95.00%
Vaccines and Related Biological Products Advisory Committee	9/17/2021	1	28	9	1	18	1	17	94.00%
Vaccines and Related Biological Products Advisory Committee	9/30/2021	1	16	0	1	15	0	15	100.00%
<b>Center for Devices &amp; Radiological Health</b>		<b>9</b>	<b>237</b>	<b>21</b>	<b>56</b>	<b>159</b>	<b>2</b>	<b>157</b>	<b>98.74%</b>
<b>Medical Devices Advisory Committee</b>									
Circulatory System Devices Panel	10/27/2021	1	25	0	5	20	0	20	100.00%
Circulatory System Devices Panel	2/17/2021	1	32	3	8	21	0	21	100.00%
Circulatory System Devices Panel	4/6/2021	1	26	2	2	22	0	22	100.00%
Circulatory System Devices Panel	8/3/2021	1	28	2	6	20	0	20	100.00%
Gastroenterology and Urology Devices Panel	7/14/2021	1	45	13	15	17	1	16	94.12%
General and Plastic Surgery Devices Panel	3/23/2021	1	22	0	9	13	0	13	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 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not Issued</u> Waivers
Neurological Devices Panel	6/3-4/2021	1	20	0	3	17	0	17	100.00%
Ophthalmic Devices Panel	11/9/2020	1	28	1	8	19	0	19	100.00%
Patient Engagement Advisory Committee	10/22/2020	1	11	0	1	10	0	10	100.00%
<b>Center for Drug Evaluation &amp; Research</b>		<b>15</b>	<b>356</b>	<b>34</b>	<b>67</b>	<b>255</b>	<b>14</b>	<b>241</b>	<b>94.51%</b>
Anesthetic and Analgesic Drug Products Advisory Committee Joint Meeting With DSaRM	11/2/2020	1	27	4	2	21	0	21	100.00%
Arthritis Advisory Committee Joint Meeting With DSaRM	3/24-25/2021	1	36	3	13	20	0	20	100.00%
Arthritis Advisory Committee	5/6/2021	1	22	0	4	18	1	17	94.44%
Cardiovascular and Renal Drugs Advisory Committee	12/15/2020	1	15	1	1	13	0	13	100.00%
Cardiovascular and Renal Drugs Advisory Committee	12/16/2020	1	15	1	1	13	0	13	100.00%
Cardiovascular and Renal Drugs Advisory Committee	7/15/2021	1	20	1	5	14	1	13	92.86%

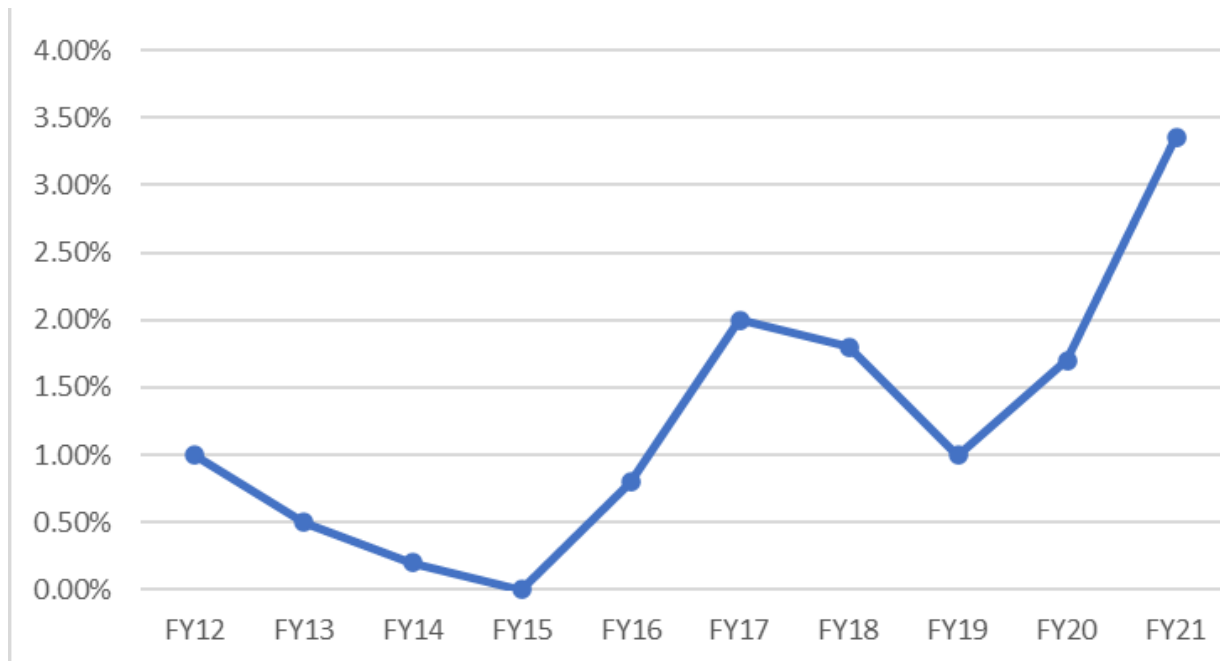


Committee Name	Meeting Date	# of Meetings	# of Persons Contacted (Attending and Not Attending) *	# of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	# of Persons Contacted and Not Serving Due to Reasons Other Than Potential Conflicts of Interest	Total Number of Meeting Participants Attending (Voting & Nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
Endocrinologic and Metabolic Drugs Advisory Committee	5/27/2021	1	21	0	4	17	0	17	100.00%
Oncologic Drugs Advisory Committee	2/9/2021	1	22	9	3	10	4	6	60.00%
Oncologic Drugs Advisory Committee	4/27-29/2021	1	44	11	12	21	6	15	71.43%
Oncologic Drugs Advisory Committee	6/24/2021	1	20	2	1	17	0	17	100.00%
Pediatric Sub-Committee of the Oncologic Drugs Advisory Committee	5/11-12/2021	1	21	1	2	18	0	18	100.00%
Peripheral and Central Nervous System Drugs Advisory Committee	11/6/2020	1	14	0	3	11	0	11	100.00%
Pharmacy Compounding Advisory Committee	6/9/2021	1	17	0	0	17	2	15	88.24%
Psychopharmacologic Drugs Advisory Committee/Drug Safety and Risk Management	10/8/2020	1	34	0	11	23	0	23	100.00%
Psychopharmacologic Drugs Advisory Committee/Drug Safety and Risk Management	10/9/2020	1	28	1	5	22	0	22	100.00%
<b>National Center for Toxicological Research</b>		<b>1</b>	<b>8</b>	<b>0</b>	<b>0</b>	<b>8</b>	<b>0</b>	<b>8</b>	<b>100.00%</b>

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 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
Science Advisory Board to the National Center for Toxicological Research	5/11-12/2021	1	8	0	0	8	0	8	100.00%
<b>Office of the Commissioner</b>		<b>1</b>	<b>19</b>	<b>0</b>	<b>2</b>	<b>17</b>	<b>0</b>	<b>17</b>	<b>100.00%</b>
Pediatric Advisory Committee	9/17/2021	1	19	0	2	17	0	17	100.00%

\* Not including industry representatives, FDA employees, and guest speakers

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



## **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 for an 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 FDA request referrals, at least every 180 days, for potential members of advisory committees from a variety of stakeholders, including (i) product developers, patient groups, and disease advocacy organizations and (ii) relevant professional societies, medical societies, academic organizations, and governmental organizations. Several times annually, FDA notifies the public about vacancies on advisory committees through *Federal Register* notices. Many professional societies use these notices to share news of potential vacancies among interested professionals. In FY 2021, FDA issued nine 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 monthly reporting on measurable objectives on FDA’s public website. As

part of that effort, the advisory committee program reports on the monthly vacancy rates by committee as well as the number of advisory committee meetings held per month.

- A staff member in FDA's Advisory Committee Oversight and Management Staff, which is in the Office of the Chief Scientist in the 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.
- 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 engaging with consumer-oriented organizations. These efforts were performed remotely in FY 2021 via direct e-mail and phone calls to such organizations.
- FDA traditionally meets with relevant organizations to explain the advisory committee program and the process for nominating candidates for advisory committee positions. FDA participated in no such activities in FY 2021 due to the COVID-19 pandemic.
- FDA traditionally distributes brochures containing advisory committee information and criteria for membership at training sessions, public advisory committee meetings, and professional scientific meetings. These activities have been severely impacted by the COVID-19 pandemic. During all virtual advisory committee meetings, a slide explaining how to apply for committee membership is shown during breaks in the meeting.
- During FY 2021, FDA disseminated recruitment information by several mass e-mailings.