

2024 Current Fiscal Year Report: Medical Devices Advisory Committee

Report Run Date: 04/25/2024 01:07:17 PM

1. Department or Agency

Department of Health and Human
Services

2. Fiscal Year

2024

3. Committee or Subcommittee

Medical Devices Advisory Committee

3b. GSA Committee

No.

916

4. Is this New During Fiscal Year?

5. Current Charter

6. Expected Renewal Date

7. Expected Term Date

No 08/18/1999

8a. Was Terminated During Fiscal Year?

8b. Specific Termination Authority

No

8c. Actual Term Date

9. Agency Recommendation for Next Fiscal Year

Continue

10a. Legislation Req to Terminate?

Not Applicable

10b. Legislation Pending?

Not Applicable

11. Establishment Authority

Authorized by Law

12. Specific Establishment Authority

21 U.S.C. 360j(f)(3)

13. Effective Date

05/28/1976

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee

Scientific Technical Program
Advisory Board

16a. Total Number of Reports

No Reports for
this Fiscal Year

17a. Open

0

17b. Closed

0

17c. Partially Closed

0

Other Activities

0

17d. Total

0

Meetings and Dates

No Meetings

Current Next
FY FY

18a(1). Personnel Pmts to Non-Federal Members	\$0.00	\$0.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$0.00	\$0.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$0.00	\$0.00
18b(2). Travel and Per Diem to Federal Members	\$0.00	\$0.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$0.00	\$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	\$0.00	\$0.00
18d. Total	\$0.00	\$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

The Medical Devices Advisory Committee provides advice to FDA on the safety and effectiveness of marketed and investigational devices, the classification of devices into one of three regulatory categories, the possible risks to health associated with the use of devices, the formulation of product development protocols, the review of premarket approval applications, and the content of guidelines or guidance documents designed to improve the interaction between the Agency and sponsors of medical devices. This committee consists of 18 advisory panels: 17 are divided according to medical specialties and one is a dispute resolution panel. In FY 2023, 7 meetings were held.

20b. How does the Committee balance its membership?

Members are drawn from the nation's top academicians, clinicians and researchers and they provide expertise in a full range of medical specialties. These medical specialties include anesthesiology, cardiac catheterization and electrophysiology, cardiology, cardiothoracic and vascular surgery, radiation physics, radiotherapy, mammography radiology, biomaterials, cytopathology, molecular genetics, clinical toxicology, chemical engineering, orthopaedic surgery, biostatistics, gastroenterology, nephrology, esophageal disorders, trauma, burn and wound plastic surgery, surgical oncology, reconstructive plastic surgery, periodontology, biochemistry, immunology, oral and maxillofacial surgery, vision sciences, corneal disease, ophthalmological surgery, perinatology, reproductive endocrinology, obstetrics and gynecology, neurology, cerebrovascular surgery, interventional neuroradiology, neurological surgery, neurological disorders and stroke, and pediatric surgery. There is at least one consumer and industry representative per panel and while they do not vote, they do provide viewpoints from their respective constituencies. Qualified females and minorities are encouraged to apply for vacancies.

20c. How frequent and relevant are the Committee Meetings?

The Committee had seven meetings in FY 2023 and tentatively plans 10 meetings for the coming year to address new technologies coming to market and to address questions that may arise about existing technologies and classification issues. The scope and depth of expertise that

Committee members possess is not always available within the Agency; therefore, the Panel meetings provide a source of expert advice to the Agency on premarket review decisions, postmarket issues, classification and reclassification decisions, early discussion of study designs, and guidance documents. During FY 2023, the Panels convened to discuss, make recommendations and vote on the following two premarket approval applications (PMAs) indicated to reduce blood pressure in patients with hypertension: (1) the ReCor Paradise Ultrasound Renal Denervation System by ReCor, Inc.; and (2) the Medtronic Symplicity Spyral multi-electrode renal denervation catheter and the Symplicity G3 RF Generator. The Panel also met to discuss, make recommendations, and vote on the clinical information related to the De Novo request for: (1) the AvertD™ test sponsored by SolvD Health, a genetic test that detects 15 single nucleotide polymorphisms that are associated with the brain reward pathway, which is intended to identify individuals at risk for developing opioid use disorder; and (2) the Usurface Meniscus Implant sponsored by Active Implants, Inc., intended to improve pain and function in the medial compartment of a knee in which the medial meniscus has been resected. The Panel discussed and made recommendations on the classification of the following ten unclassified, preamendment device types: tissue expanders and accessories; mammary sizers; wound dressings; absorbable synthetic wound dressings, topical hemostatic wound dressing; nail prostheses; ultrasonic surgical instruments; single-use reprocessed ultrasonic surgical instruments; neurosurgical ultrasonic instruments; and ophthalmic dispensers. Additionally, the Panel made recommendations regarding a potential

future reclassification of the following three devices: nucleic acid and serology-based in vitro diagnostic devices indicated for use to aid in diagnosis of hepatitis B; serology-based in vitro diagnostic devices indicated for use to aid in the detection of past, recent, or current infection with human parvovirus B19; and cell-mediated immune reactivity in vitro diagnostic devices indicated for use to aid in identification of in vitro responses to peptide antigens that are associated with Mycobacterium Tuberculosis infection. The Panel also discussed and made recommendations and/or advice to FDA on: (1) ongoing concerns that pulse oximeters may be less accurate in individuals with darker skin pigmentation; and (2) in vitro diagnostic devices used in pandemic preparedness and response to satisfy, in part, a requirement under the Food and Drug Omnibus Reform Act of 2022 (FDORA). The pulse oximeters meeting topic was considered controversial.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Committee members are selected from academia, research, and/or clinical practice. The advice they provide helps decisions stand up under public scrutiny and offers credibility to the regulatory process. The goals of the committee can only be met using these alternate means to obtain sound advice.

20e. Why is it necessary to close and/or partially closed committee meetings?

N/A

21. Remarks

The Panels of this Committee meet as needed, rather than on a regular basis; therefore, some

Panels did not meet during FY 2023 and have no reporting requirements. For the Panels that did not meet, considerable time was also devoted to reappointing current members, maintaining associated records for these activities, and streamlining paper processes within FDA. In addition, time was spent in the routine care and maintenance of the committee: the development of a financial report for this website; updating the roster and number of vacancies on our website; completing the annual ethics report; reviewing financial disclosures of current members and nominees and providing ethics training. Updates on the following committee Members: Grace Hyun J. Kim profile was added back to the list of committee members because her profile did not appear as a committee member in 2023. For FY 2022, Dr. Kim was identified under Committee Detail # CD - 1571511 . The following committee members resigned in FY 2023: Wendi A. Berg, MD (10/18/2022), Brent Blumenstein, Ph.D. (10/25/2022), Maureen Finnegan (12/18/2022); Donald Leopold (12/6/2022), Robert Burr (04/10/2023); Atzal Siddiqui (12/7/2022); Gregory Tsongalis (8/24/2023); Noel V. Stanton (08/14/2023), and Edward Chin (09/11/2023). Their termination date is added to their profile data (committee member information section).

Designated Federal Officer

James P. Swink Lead Public Health Analyst,
Center for Devices and Radiological Health/FDA

Committee Members	Start	End	Occupation	Member Designation
Al-Aswad, Lama	04/29/2019	10/31/2024	Professor of Ophthalmology and Vice Chair of Innovations, New York Univ. Langone Eye Center, New York, NY	Special Government Employee (SGE) Member

Alam, Murad	04/23/2022	08/31/2025	Vice-Chair, Department of Dermatology, Northwestern University, Chicago, IL	Special Government Employee (SGE) Member
Alexander, Barbara	07/18/2022	02/28/2026	Professor of Medicine and Pathology, Duke University, Durham, NC	Special Government Employee (SGE) Member
Allen, Keith	08/31/2020	06/30/2024	Dir., of Surgical Research/Co-Dir., Structural Heart, St. Luke's Hospital of Kansas City, Kansas City, MO	Special Government Employee (SGE) Member
Ascher, Susan	04/11/2023	01/31/2027	Professor Radiology, Georgetown Univ. School of Medicine, Washington DC	Special Government Employee (SGE) Member
Badylak, Stephen	06/30/2022	02/28/2026	Deputy Director, McGowan Institute for Regenerative Medicine, University of Pittsburgh, Pittsburgh, PA	Special Government Employee (SGE) Member
Barber, Thomas	08/29/2023	08/31/2026	Prof., Arthritis and Joint Replacement, Univ. of California, San Francisco, Orthopedic Institute, San Francisco, CA	Special Government Employee (SGE) Member
Beavis, Kathleen	07/18/2022	02/28/2026	Professor of Pathology, University of Chicago, Chicago, IL	Special Government Employee (SGE) Member
Berg, Joel	11/14/2019	10/31/2023	Professor Emeritus, Pediatric Dentistry, Univ. of Washington, School of Dentistry, Seattle, WA	Special Government Employee (SGE) Member
Berry, Donald	06/30/2022	02/28/2026	Professor, Department of Biostatistics, the University of Texas M.A.D. Anderson Cancer Center	Special Government Employee (SGE) Member
Blakenship, James	07/01/2019	06/30/2026	Prof. of Medicine and Director, Div., of Cardiology, Univ. of New Mexico, Albuquerque, NM	Special Government Employee (SGE) Member
Bonnell, Stacey	09/01/2020	08/31/2024	Global Leader, Regulatory Affairs, Nuvasive, Inc., San Diego, CA	Representative Member

Bourland, J	04/11/2023	01/31/2027	Prof., Departments of Radiation Oncology, Biomedical Engineering and Physics, Wake Forest Univ. School of Medicine, Winston-Salem, NC	Special Government Employee (SGE) Member
Branson, Richard	04/09/2019	11/30/2023	Professor, Dept. of Surgery, Div. of Trauma & Critical Care, Univ. of Cincinnati, Cincinnati, OH	Special Government Employee (SGE) Member
Bremer, Andrew	04/25/2017	02/29/2024	Chief, Pediatric Growth and Nutrition Branch, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, MD	Regular Government Employee (RGE) Member
Bressler, Neil	04/29/2019	10/31/2024	Professor of Ophthalmology, Johns Hopkins University School of Medicine, Baltimore, MD	Special Government Employee (SGE) Member
Brindis, Ralph	07/01/2022	06/30/2025	Clinical Professor of Medicine, Department of Medicine & the Philip R. Lee Institute for Health Policy Studies, University of California, San Francisco	Special Government Employee (SGE) Member
Brown, A	04/20/2023	11/30/2027	Transplant Pulmonologist, Inova Advanced Lung Disease and Transplant Program, Falls Church, VA	Special Government Employee (SGE) Member
Brummert, Rachel	01/19/2017	08/31/2024	Consumer Representative; President, Quinolone Vigilance, Charlotte, NC	Special Government Employee (SGE) Member
Bryant, P.	09/01/2020	08/31/2024	World Wide Vice President, Regulatory Affairs, Ethicon, Inc., Somerville, NJ	Representative Member
Carrino, John	04/01/2022	01/31/2026	Professor of Radiology, Weill Medical College of Cornell University, New York, NY	Special Government Employee (SGE) Member

Cassiere, Hugh	03/30/2018	11/30/2026	Associate Prof. South Shore Hospital, Bay Shore, NY	Special Government Employee (SGE) Member
Cetnarowski, Wes	10/05/2022	06/30/2026	Sr. Vice President Scientific Affairs, Chief Medical Officer, B Braun Medical, Inc., Center Valley, PA	Representative Member
Chappell, Richard	02/01/2020	01/31/2024	Prof., Dept. of Biostatistics and Medical Informatics, Univ. of Wisconsin Madison Medical School, Madison, WI	Special Government Employee (SGE) Member
Chew, Emily	12/19/2020	12/31/2024	Director, Division of Epidemiology and Clinical Applications, National Eye Institute, National Institutes of Health, Bethesda, MD	Regular Government Employee (RGE) Member
Cigarroa, Joaquin	07/01/2022	06/30/2025	Division Head of Cardiology, Clinical Chief Knight CV Institute, Melvin Judkins Endowed Professor of Cardiology, Professor of Medicine, Oregon Health and Sciences University, Portland, Oregon	Special Government Employee (SGE) Member
Coleman, Bernice	09/13/2022	02/28/2025	Consumer Representative; Assistant Professor, Biomedical Sciences and Medicine, Cedars Sinai Medical Center, Los Angeles, CA	Special Government Employee (SGE) Member
Connor, Jason	07/01/2019	06/30/2026	President & Lead Statistical Scientist, ConfluenceStat, LLC, Orlando, FL	Special Government Employee (SGE) Member
Cormier, Jason	10/27/2022	10/27/2027	Neurosurgeon, Acadiana Neurosurgery	Special Government Employee (SGE) Member
DeLong, Michael	09/01/2022	08/31/2026	Assistant Professor in Residence, University of California, Los Angeles	Special Government Employee (SGE) Member

			Vice President, Regulatory Affairs, Policy and Intelligence	
Desjardins, Philip	10/01/2017	09/30/2025	Medical Devices Diagnostics, Johnson and Johnson, New Brunswick, NJ	Representative Member
Deverall, Miranda	03/28/2023	02/28/2027	Director, Regulatory Affairs, Becton Dickinson, Sparks, MD	Representative Member
Dominitz, Jason	03/09/2021	12/31/2024	National Program Director, Gastroenterology, Department of Veterans Affairs, VA Puget Sound Health Care System, Seattle Div., Seattle, WA	Regular Government Employee (RGE) Member
Edwards, Veverly	12/14/2017	11/30/2025	Consumer Representative:Affiliate Broker, First National Realty, Memphis, TN	Special Government Employee (SGE) Member
Espey, Eve	09/26/2023	01/31/2028	Chair, Dept., Ob/Gyn, Univ. of New Mexico Health Sciences Center School of Medicine, 1 University of Mexico, Albuquerque, NM	Special Government Employee (SGE) Member
Evans, Scott	09/01/2023	08/31/2027	Dir., The Biostatistics Ctr, Prof. and Founding Chair, Dept. Biostatistics and Bioinformatics, Milken Institute School of Public Health, George Washington Univ., Rockville, MD	Special Government Employee (SGE) Member
Ferreira-Gonzalez, Andrea	08/18/2023	05/31/2027	Prof. of Pathology and Chair, Div., of Molecular Diagnostics, Virginia Commonwealth Univ., Richmond, VA	Special Government Employee (SGE) Member
Galandiuk, Susan	09/01/2022	08/31/2026	Professor, Department of Surgery, Director of Price Institute of Surgical Research, University of Louisville, Louisville, KY	Special Government Employee (SGE) Member
Geaghan, Sharon	03/30/2021	02/28/2025	Professor Emerita, Dept. of Pathology and Pediatrics, Stanford University School of Medicine, Menlo Park, CA	Special Government Employee (SGE) Member

Gelato, Marie	04/25/2017	02/29/2024	Division of Endocrinology, Department of Medicine Health Science Center, SUNY at Stony Brook, Stony Brook, NY	Special Government Employee (SGE) Member
Gooden, Cheryl	04/20/2023	11/30/2027	Associate Professor of Anesthesiology and Pediatrics, Dept. of Anesthesiology, Yale School of Medicine, New Haven, CT	Special Government Employee (SGE) Member
Hamlin, Lise	09/11/2019	10/31/2023	Director of Public Policy, Hearing Loss Association of America, Bethesda, MD	Special Government Employee (SGE) Member
Harris, Hobart	04/23/2022	08/31/2025	Professor of Surgery, University of California, San Francisco	Special Government Employee (SGE) Member
Hirshfeld, Jr., John	10/31/2018	09/30/2024	Professor of Medicine, Perelman School of Medicine, University of Pennsylvania School of Medicine, Philadelphia, PA	Special Government Employee (SGE) Member
Hoofnagle, Andrew	08/30/2022	02/28/2025	Professor and Head, Division of Chemistry, University of Washington Medical Center, Seattle, WA	Special Government Employee (SGE) Member
Iglesia, Cheryl	07/18/2022	01/31/2025	Director, Section of Female Pelvic Medicine and Reconstructive Surgery, MedStar Washington Center, Washington, DC	Special Government Employee (SGE) Member
Jarvis, William	04/12/2019	12/31/2023	President and Medical Consultant, Jason and Jarvis Associates, Hilton Head Island, SC	Special Government Employee (SGE) Member
Jeng, Bennie	05/27/2022	10/31/2025	Professor and Chair, Department of Ophthalmology Scheie Eye Institute, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA	Special Government Employee (SGE) Member

Jennings, Lisa	01/31/2023	02/28/2026	Prof., College of Graduate Health Sciences, Univ. of Tennessee Health Sciences Center, Memphis, TN	Special Government Employee (SGE) Member
Jensen, Mary	06/02/2021	11/30/2024	Professor, University of Virginia, Charlottesville, VA	Special Government Employee (SGE) Member
Johnston, Karen	06/02/2021	11/30/2023	University of Virginia Health System, Dept. of Neurology, Charlottesville, VA	Special Government Employee (SGE) Member
Kalota, Susan	08/20/2021	12/31/2025	Private Practice, Urologic Associates of Southern Arizona	Special Government Employee (SGE) Member
Kim, Grace Hyun	09/27/2018	01/31/2026	Prof. in Residence, Dept. of Radiological Sciences & Biostatistics, Univ. of California, Los Angeles, Los Angeles, CA	Special Government Employee (SGE) Member
Kirkpatrick, John	08/29/2023	08/31/2026	Orthopaedic Surgeon, Orlando Veterans Administration Medical Center, Orlando, FL	Regular Government Employee (RGE) Member
Kost, Gerald	01/31/2023	02/28/2026	Emeritus Professor, Pathology and Laboratory Medicine, Univ. of California-Davis, School of Medicine, Sacramento, CA	Special Government Employee (SGE) Member
Kraus, Stephen	03/09/2021	12/31/2023	Professor and Vice Chairman, Medical Director, Department of Urology, University of Texas Health, San Antonio, San Antonio, TX	Special Government Employee (SGE) Member
Krupinski, Elizabeth	04/23/2022	01/31/2025	Professor and Vice Chair for Research, Department of Radiology & Imaging Sciences, Emory University, NE Atlanta, GA	Special Government Employee (SGE) Member

La Hoz, Ricardo	07/18/2022	02/28/2025	Associate Professor of Internal Medicine, Department of Medicine, University of Texas Southwestern Medical Center, Dallas, TX	Special Government Employee (SGE) Member
Lalwani, Anil	04/09/2019	10/31/2023	Professor and Chair for Research, Columbia Univ. College of Physicians and Surgeons, New York, NY	Special Government Employee (SGE) Member
Larson, Floyd	02/11/2020	10/31/2023	President/Senior Consultant, PaxMed International, LLC, San Diego, CA.	Representative Member
Laskey, Warren	12/13/2018	09/30/2026	Professor, Division of Cardiology University of Mexico School of Medicine	Special Government Employee (SGE) Member
Lerner, Noah	06/13/2023	02/28/2027	Director Regulatory Affairs, Abbott Laboratories, Diagnostic Division	Representative Member
Lew, Susie	12/14/2020	12/31/2024	Professor, Department of Medicine, George Washington University Medical Center, Washington, DC	Special Government Employee (SGE) Member
Ling, Frank	07/18/2022	01/31/2025	Women's Health Specialists, PLLC, Germantown, TN	Special Government Employee (SGE) Member
Lipkin, Steven	04/12/2019	05/31/2026	Gladys and Roland Harriman Professor of Medicine and Vice Chair for Research, Dept. of Medicine, Weill Cornell Medical College, Cornell Univ., New York, NY	Special Government Employee (SGE) Member
Lively, Tracy	06/30/2022	02/28/2026	Deputy Associate Director, Cancer Diagnosis Program, National Cancer Institute/National Institutes of Health, Rockville, MD	Regular Government Employee (RGE) Member
Loftspring, Edward	03/16/2023	12/31/2026	Consumer Representative; Director, United Ostomy Association of America, Kennebunk, ME	Special Government Employee (SGE) Member

Lyden, Patrick	06/02/2021	11/30/2023	Professor of Physiology and Neuroscience, Keck School of Medicine of USC, Los Angeles, CA	Special Government Employee (SGE) Member
Manner, Paul	09/01/2023	08/31/2027	Professor, Dept. of Orthopaedic and Sports Medicine, Univ. of Washington School of Medicine, Seattle, WA	Special Government Employee (SGE) Member
Manzi-Muhire, Remy	02/22/2023	12/31/2027	Sr., Clinical Product Risk Specialist, Boston Scientific Endoscopy, Marlborough, MA	Representative Member
McKee, Amy	08/30/2022	02/28/2025	Assistant Professor, University of Colorado, Anschutz Medical Campus, Aurora, CO 80045	Special Government Employee (SGE) Member
Moore, Lisa	09/26/2023	01/31/2027	Prof. of Maternal-Fetal Medicine, Dept. of OB/GYN, Texas Tech Permian Basin Health Sciences, Odessa, TX	Special Government Employee (SGE) Member
Moore, Thomas	07/18/2022	02/28/2026	ID Consultants, PA, Wichita, KS	Special Government Employee (SGE) Member
Morgan, Charity	01/01/2015	12/31/2023	Associate Professor, Dept. of Biostatistics, Univ. of Alabama at Birmingham, Birmingham, AL	Special Government Employee (SGE) Member
Morgan, Daniel	02/01/2020	01/31/2024	Clinical Prof., Ob/Gyn, Univ. of Michigan, Women Hospital, Ann Arbor, MI	Special Government Employee (SGE) Member
Moscicki, Anna-Barbara	07/18/2022	02/28/2025	Chief, Adolescent & Young Adult Medicine, University of California, Los Angeles	Special Government Employee (SGE) Member
Pearson, Cynthia	08/29/2023	01/31/2027	Consumer Representative; Former Executive Director, National Women's Network, University Park, MD	Special Government Employee (SGE) Member
Pokrop, Frank	07/09/2020	02/28/2024	Director, Regulatory Affairs, Quidel, Inc., San Diego, CA.	Representative Member
Pollard, K	06/30/2022	02/28/2025	Associate Professor, Department of Molecular Medicine, Scripps Research Institute, LaJolla, CA	Special Government Employee (SGE) Member

Price, Amy	02/03/2021	09/30/2024	Consumer Representative; Sr. Research Scientist, Stanford University School of Medicine, Stanford University, Stanford, CA	Special Government Employee (SGE) Member
Pulido, Jose	09/13/2022	10/31/2026	Larry Donoso Chair of Translational Ophthalmology, Wills Eye Hospital, Philadelphia, PA	Special Government Employee (SGE) Member
Punjabi, Naresh	04/09/2019	11/30/2023	Professor of Medicine and Epidemiology, Johns Hopkins Univ. School of Medicine and Bloomberg School of Public Health, Baltimore, MD	Special Government Employee (SGE) Member
Rajpal, Rajesh	11/01/2022	10/31/2026	Chief Medical Officer and Global Head of Clinical and Medical Affairs, Johnson & Johnson Vision, N. Jacksonville, FL	Representative Member
Remaley, Alan	03/30/2021	02/29/2024	Sr. Investigator-Section Chief, Lipoprotein Metabolism Lab, National Heart, Lung and Blood Institute, National Institutes of Health, Bethesda, MD	Regular Government Employee (RGE) Member
Repka, Michael	05/27/2022	10/31/2025	David L. Guyton, MD and Feduniak Family Professor of Ophthalmology, Professor of Pediatric Medicine, John Hopkins University School of Medicine, Baltimore, MD	Special Government Employee (SGE) Member
Rivera, Arnaldo	04/09/2019	10/31/2023	Associate Professor Otolaryngology, Univ. of Missouri School of Medicine, Columbia, MO	Special Government Employee (SGE) Member
Roselle, Gary	04/11/2022	12/31/2025	National Program Executive Director, National Infectious Diseases Service, Department of Veterans Affairs/Veterans Health Administration, Cincinnati, OH	Regular Government Employee (RGE) Member

Sauer, Nancy	06/17/2023	12/31/2026	Sr. Dir., Regulatory Affairs, Medtronic Surgical Innovations, Lafayette, CO	Representative Member
Schwaitzberg, Steven	01/01/2017	12/31/2023	Professor and Chairman, Dept. of Surgery, Jacobs School of Medicine and Biomedical-Sciences Univ. at Buffalo-The State Univ. of New York, Buffalo, NY	Special Government Employee (SGE) Member
Shaheen, Nicholas	03/01/2023	12/31/2026	Co-Dir., North Carolina Translational & Clinical Sciences Inst., Univ. of North Carolina, Chapel Hill, NC	Special Government Employee (SGE) Member
Skates, Steven	09/20/2023	05/31/2025	Associate Prof. of Medicine (Biostatistics), Massachusetts General Hospital, Boston, MA	Special Government Employee (SGE) Member
Smith, Harvey	09/30/2016	08/31/2024	Assistant Professor of Orthopaedic Surgery at the Veteran's Administration, Philadelphia, PA	Regular Government Employee (RGE) Member
Snyder, Russell	09/26/2023	01/31/2027	Vice Chairman, Dept. of OB/GYN, the Univ. of Texas Medical Branch, Galveston, TX	Special Government Employee (SGE) Member
Solomon, Stephen	04/23/2022	01/31/2025	Professor, Weill Cornell Medical College, Chief of Interventional Radiology, Department of Radiology, Memorial Sloan Kettering Cancer Center, New York, NY	Special Government Employee (SGE) Member
Somers, Emily	08/30/2022	02/28/2025	Professor, School of Medicine & Public Health, Department of Internal Medicine, University of Michigan, Ann Arbor, MI	Special Government Employee (SGE) Member
Spring, Bradford	10/09/2022	02/28/2027	Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corp., Indianapolis, IN	Representative Member

St. George, Kristen	07/18/2022	02/28/2025	Chief Laboratory of Viral Diseases, New York State Department of Health, Wadsworth Center, Albany, NY	Special Government Employee (SGE) Member
Starling, Randall	01/21/2020	06/30/2026	Prof. of Medicine, Dept. of Cardiovascular Medicine, Section of Heart Failure and Transplant Medicine, Heart, Vascular and Thoracic Inst., Cleveland Clinic, Cleveland, OH	Special Government Employee (SGE) Member
Subhawong, Ty	08/29/2023	08/31/2026	Prof. of Clinical Radiology and Director, Div., Musculoskeletal, Dept. of Radiology, Univ. of Miami Miller School of Medicine, Miami, FL	Special Government Employee (SGE) Member
Telem, Dana	03/09/2021	12/31/2024	Associate Professor of Surgery, University of Michigan, Ann Arbor, MI	Special Government Employee (SGE) Member
Tjoumakaris, Stavropoula	06/02/2021	11/30/2024	Professor of Neurological Surgery, Thomas Jefferson University, Philadelphia, PA	Special Government Employee (SGE) Member
Van Der Pol, Barbara	01/28/2019	02/28/2026	Professor of Medicine, Univ. of Alabama at Birmingham	Special Government Employee (SGE) Member
Wang Memoli, Jessica	04/20/2023	11/30/2027	Director, Bronchoscopy and Interventional Pulmonary, MedStar Washington Hosp. Ctr., Washington, DC	Special Government Employee (SGE) Member
Wang, Lili	01/31/2023	02/28/2026	Research Chemist, Biosystems and Biomaterials Division, National Institute of Standards and Technology, Gaithersburg, MD	Special Government Employee (SGE) Member
Wang, Ping	03/30/2021	02/28/2025	Professor of Pathology and Laboratory Medicine, University of Pennsylvania, Philadelphia, PA	Special Government Employee (SGE) Member

Weiss, Jayne	05/27/2022	10/31/2025	Chair, Department of Ophthalmology, Associate Dean of Clinical Affairs, Louisiana State University School of Medicine, New Orleans, Louisiana Chief Medical Officer, SVP for Clinical Research and Medical Affairs, Masimo, Inc., Irvine, CA Global Head, Regulatory Affairs, Roche Diagnostics Solution, Pleasanton, CA	Special Government Employee (SGE) Member
Wilson, William	09/06/2022	11/30/2026	Senior Regulatory Affairs Manager, Boston Scientific Corp.	Representative Member
Winslow, Nathan	02/09/2023	05/31/2027	Assoc. Prof. of Medicine and Oncology/Dir. Div., Pulmonary and Critical Care Medicine, Johns Hopkins Univ. Schol of Med., Baltimore, MD	Representative Member
Wreh, Elijah	12/01/2017	11/30/2026	Dir., Richard A. and Susan F. Smith Ctr. for Outcomes Research in Cardiology, Beth Israel Deaconess Medical Ctr., Boston, MA	Representative Member
Yarmus, Lonny	03/30/2018	11/30/2024	Professor of Radiology, Vice Chair, Quality and Strategic Development, Division Chief, Breast Imaging, Department of Radiology, University of Pittsburgh Medical Center, Pittsburgh, PA	Special Government Employee (SGE) Member
Yeh, Robert	08/31/2020	06/30/2024		Special Government Employee (SGE) Member
Zuley, Margarita	04/23/2022	01/31/2025		Special Government Employee (SGE) Member

Number of Committee Members Listed: 112

Narrative Description

FDA's strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special

populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Panels (of the Medical Devices Advisory Committee (MDAC)) of the Center for Devices and Radiological Health (CDRH) Advisory Committee organized under 513(b) of the Federal Food, Drug and Cosmetic Act supports the FDA mission and strategic plan by providing independent expert scientific advice on the safety and efficacy of medical devices and radiation emitting products. The Panels also offer an opportunity for public input on all the issues that attend the introduction of new medical devices.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	<input checked="" type="checkbox"/>
Trust in government	<input checked="" type="checkbox"/>
Major policy changes	<input checked="" type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input type="checkbox"/>
Increased customer satisfaction	<input checked="" type="checkbox"/>
Implementation of laws or regulatory requirements	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	<input type="checkbox"/>
Unable to Determine	<input checked="" type="checkbox"/>
Under \$100,000	<input type="checkbox"/>
\$100,000 - \$500,000	<input type="checkbox"/>

\$500,001 - \$1,000,000
\$1,000,001 - \$5,000,000
\$5,000,001 - \$10,000,000
Over \$10,000,000
Cost Savings Other

☐
☐
☐
☐
☐

Cost Savings Comments

The utilization of Medical Devices Advisory Committee enables the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The services of the Committee resulted in advice for the improvement of the public health for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

359

Number of Recommendations Comments

The Committee made 359 recommendations from FY03 through FY23.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

85%

% of Recommendations Fully Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

10%

% of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the

advice. This number represents an approximation of the percentage of recommendations that the agency has fully implemented or plans to fully implement.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☒ No ☐ Not Applicable ☐

Agency Feedback Comments

It usually does. Product approval issues are first released to the sponsor. When appropriate information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

Reorganized Priorities	<input checked="" type="checkbox"/>
Reallocated resources	<input type="checkbox"/>
Issued new regulation	<input checked="" type="checkbox"/>
Proposed legislation	<input type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

Action Comments

FDA approves or chooses not to approve an investigational new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

Checked if Applies

Contact DFO	<input checked="" type="checkbox"/>
Online Agency Web Site	<input checked="" type="checkbox"/>
Online Committee Web Site	<input checked="" type="checkbox"/>
Online GSA FACA Web Site	<input checked="" type="checkbox"/>
Publications	<input checked="" type="checkbox"/>

Other



Access Comments

N/A