Bethesda North Marriott Hotel and Conference Center

Feb 22, 2027 7:00 AM - Feb 23, 2027 5:00 PM

5701 Marinelli Road, North Bethesda, MD 20852

Advertising and Promotion Regulatory Affairs Conference

Advancing Advertising and Promotion in the Age of Innovation

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Early Bird Rates End



Print Agenda

Day 1 Feb 22, 2027

7:30 AM — 8:20 AM

Networking Breakfast

7:30 AM — 5:25 PM

Registration

8:15 AM — 8:30 AM

Welcome and Opening Remarks

Welcome and Opening Remarks
Track: General Session

Session Chair(s)



Tamei Elliott, MS

Director, Global Scientific Content
DIA, United States

Tamei Elliott, MS, is the Director of Global Scientific Content at the Drug Information Association (DIA). She leads DIA's global scientific content strategy, ensuring alignment with regulatory priorities, industry trends, and evolving stakeholder needs across regions. She also established and leads DIA's Global Science Content Center of Excellence, driving harmonization of content development and strategy across Europe, Asia, North Africa, and the Middle East. With expertise in regulatory science, she brings stakeholders together to address the life sciences industry's most pressing challenges, driving outcomes that move toward solutions.

8:30 AM — 9:30 AM

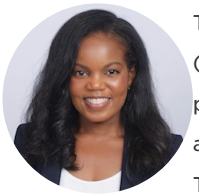
Session 1: FDA Advertising & Promotion Updates: What Industry Needs to Know to Navigate Regulatory Expectations

Hear directly from FDA representatives on recent developments, regulatory priorities, and emerging considerations in prescription drug advertising and promotion Gain insights into the evolving regulatory landscape and key areas of interest for industry stakeholders.
Track: General Session

Session Chair(s)

Twyla Mosey, PharmD

Acting Office Director, OPDP, CDER
FDA, United States



Twyla Mosey, PharmD, RPh is the Acting Director of the Office of Prescription Drug Promotion (OPDP) at the Food and Drug Administration. She ensures that OPDP fulfills its mission of protecting the public health by overseeing office operations including compliance activities, advisory and labeling recommendations, and external outreach activities. Over the past 18 years, Twyla has held various leadership roles within the Agency and pharmaceutical industry. She received her Doctor of Pharmacy degree from Florida Agricultural and Mechanical University and completed several fellowships including a Post-Doctoral Pharmaceutical Industry Fellowship.

Speaker(s)



Speaker

Representative Invited

FDA, United States

Kristine T. Khuc has been with the FDA, Center for Biologics Evaluation and Research (CBER) since 2011. She now serves as Acting Branch Chief in the Office of Compliance and Biologics Quality (OCBQ), Advertising and Promotional Labeling Branch (APLB). In her current position, she has experience in reviewing and evaluating advertising and promotional labeling. She came from the Center for Drug Evaluation and Research (CDER) in the Division of Advisory Committee and Consultant Management. She received a Doctor of Pharmacy degree from Howard University and completed a drug information residency program at Washington Hospital Center. Prior to FDA, she practiced at the Fairfax Health Center and at the Andrew Rader Health Clinic.



Speaker

Representative Invited

FDA, United States

Kathryn Dennehy is a Veterinary Medical Officer at the FDA Center of Veterinary Medicine. She works in the Division of Pharmacovigilance and Surveillance and is responsible for monitoring the safety and effectiveness of animal drugs after they are marketed as well as the promotion and advertising of animal drugs. Prior to joining the FDA, Dr. Dennehy worked as a small animal associate veterinarian in a private practice in Northern Virginia. She received her BS from The College of William and Mary, and her DVM from the Virginia-Maryland College of Veterinary Medicine.



Speaker

Representative Invited

FDA, United States

Deborah Wolf has been a regulatory counsel in CDRH since 1995, focusing primarily on issues related to labeling and advertising. She advises staff in many parts of CDRH on a broad range of device-related policy and regulatory issues and engages with the other medical product centers on Agency policy discussions and document development.

9:30 AM — 10:30 AM

Session 2: NAD and Industry Perspectives: A Year in Review and Practical Lessons

Review recent National Advertising Division (NAD) cases, actions, outcomes, processes and timelines, including lessons learned from emerging advertising and promotion challenges. Explore practical considerations for evaluating regulatory and self-regulatory developments, including implications for internal processes, standard operating procedures, promotional materials, and cross-functional coordination.

Learning Objective :

At the conclusion of this session, participants will be able to:

- Evaluate the impact of recent NAD and legal actions on promotional materials and identify compliance risks.
- Analyze emerging challenges in NAD/legal decisions.
- Identify substantiation gaps that contribute to adverse rulings by non-FDA agencies.

Track: General Session

Session Chair(s)



Darshan Kulkarni, JD, PharmD, MS, RPh

Principal Attorney
Kulkarni Law Firm, PC, United States

Darshan Kulkarni is a pharmacist-attorney at the Kulkarni Law firm and advises life sciences companies on promotional compliance and medical affairs strategy. He works with pharmaceutical and medical device teams on FDA advertising rules, OPDP risk, influencer and digital promotion, speaker programs, scientific exchange, HCEI communications, and field medical guardrails. Drawing on hands-on experience in compliance, clinical research, and regulatory strategy, he helps companies design review processes, train commercial and medical teams, and navigate enforcement risk while preserving scientific integrity and business objectives.

Speaker(s)



Speaker

Representative Invited

BBB National Programs, United States

Phyllis Marcus serves as Vice President, BBB National Programs' National Advertising Division. In this role, Marcus leads a team of attorneys and professionals at BBB National Programs' National Advertising Division holding national advertising across all media types to high standards of truth and accuracy by reviewing truth-in-advertising challenges from businesses, trade associations, consumers, or on its own initiative. Through its work, thousands of misleading advertising claims have been removed from the marketplace and its case decisions represent the single largest body interpreting advertising law in the country.

10:30 AM — 11:15 AM

Networking Break

11:15 AM — 12:30 PM

Session 3: Building Defensible Medical and Scientific Communications: Current Strategies and Best Practices

Speaker(s)



Session 3: Building Defensible Medical and Scientific Communications: Current Strategies and Best Practices Joshua Oyster, JD

Partner
Ropes & Gray, United States

Josh Oyster is a partner in Ropes & Gray's Life Sciences Regulatory & Compliance practice. He steers clients through a wide range of FDA regulatory issues to help them bring innovative products to market while also ensuring regulatory compliance. Josh is frequently tapped to analyze clients' toughest questions related to complex or ambiguous regulatory requirements, drawing on his extensive experience with key policy and enforcement priorities, including medical product promotion. In addition, Josh routinely helps companies navigate FDA inspections and other compliance and enforcement matters and also assists clients in assessing regulatory risks associated with potential acquisitions and investments.



Speaker

Representative Invited

Sidley Austin LLP, United States

Torrey Cope advises and represents clients in a full range of regulatory, enforcement, litigation, and transactional matters involving FDA issues. He has been recognized as a "Life Sciences Star" in the FDA: Pharmaceutical category by LMG Life Sciences since 2016 and has been included in The Best Lawyers in America for FDA Law since 2018.



Speaker

Representative Invited

Eli Lilly and Company , United States

Mike Sauers is Director in Eli Lilly's Global Regulatory Affairs - US Advertising and Promotion group, advising on promotional compliance across the range of Lilly's Oncology, Diabetes, and Biomedicines US marketed products. Prior to joining Lilly in 2017, Mike served for 10 years in the FDA's Office of Prescription Drug Promotion. His previous work includes posts in the HHS Office of the Secretary and with Pfizer as a Healthcare Representative. Mike received his Bachelor's Degree in Neuroscience from the University of Delaware and a Master's of Public Policy from Georgetown University.

Learning Objective :

At the conclusion of this session, participants will be able to:

- Apply best practices for early planning and cross-functional collaboration in medical and scientific communications.
- Identify key regulatory considerations for pipeline communications, scientific information on unapproved uses (SIUU), and scientific exchange.
- Evaluate whether medical and scientific communications align with current FDA expectations for evidence substantiation.

12:30 PM — 1:30 PM

Networking Luncheon

1:30 PM — 2:45 PM

Session 4: Breaking Down Silos: Strengthening Cross-Functional Alignment to Improve Promotional Review and Execution

Discuss cross-functional strategies and operational considerations in advertising and promotion, drawing on practical experiences and perspectives form industry speakers. The session will be shaped by the selected abstract contributors and their proposed topics.
Learning Objective : Highlight real world examples for product launches where regulatory advertising and promotion in clinical development and label creation would have led to more strategic outcomes Understand risks of submitting data and studies that do not clearly support product approval Strategically assess phase 3 study protocols to include endpoints to support CFL data presentation at launch
Track: General Session

Session Chair(s)



Gina Vestea, PharmD

Head, Global Regulatory Affairs Advertising & Promotion
Sanofi, United States

As the Head of the Global Regulatory Advertising & Promotion, Gina leads the teams responsible for the US and Global review of Sanofi product portfolios. She has worked in numerous therapeutic areas during her 17 years with Sanofi. Her experience includes supporting numerous product launches and has been responsible for broad post-marketing regulatory activities beyond advertising and promotion. Gina has previously held various roles within the pharmaceutical industry on advertising & promotion and medical teams. Gina is a licensed pharmacist and received her Doctor of Pharmacy Degree from the Ernest Mario School of Pharmacy at Rutgers University. She is also a graduate of the Rutgers Institute for Pharmaceutical Industry Fellowships.

Speaker(s)



Beyond Launch: Bringing Ad Promo Regulatory Strategy Upstream in Drug Development

Representative Invited

H. Lundbeck A/S, Denmark



Incorporating Regulatory Advertising and Promotion Interests into Clinical Development

Representative Invited

Opus Regulatory LLC, United States

Gregory Ringenberg, Pharm.D., M.S., RUCIF, R.Ph., is a Consulting VP at ProPharma Group specializing in regulatory and medical affairs with nearly 20 years of experience. He provides expertise for programs spanning small molecules, biologics, and medical devices. Specializing in FDA advertising, promotion, and labeling regulations, he's been the regulatory lead on over 80 product launches, has established review frameworks and process improvement for multiple companies, and has provided guidance to companies requiring remedial efforts. He has a strong focus on accelerated approvals and rare/orphan diseases.

2:45 PM — 3:30 PM

Networking Break

3:30 PM — 4:30 PM

Session 5: Navigating Change: Building Skills and Preparing for the Future of Advertising and Promotion

This multigenerational panel will bring together professionals at various career stages to share perspectives on career development, evolving skills and competencies, and navigating today's changing advertising and promotion regulatory affairs landscape. Panelists will explore how current industry challenges are shaping workforce needs, opportunities for professional growth, and strategies for preparing the next generation of regulatory affairs professionals for the future.
Track: General Session

Session Chair(s)

John Paul Marcus, PharmD

Executive Director, Regulatory Compliance
Ionis Pharmaceuticals, United States



4:30 PM — 5:30 PM

Networking Reception

Day 2 Feb 23, 2027

8:00 AM — 8:45 AM

Networking Breakfast

8:00 AM — 3:00 PM

Registration

8:45 AM — 9:00 AM

Welcome to Day 2 and Update from AdPromo Working Group

9:00 AM — 10:00 AM

Session 6: Navigating Pre-Approval Communications: Developing Compliant Strategies Across the Product Lifecycle

Discuss strategies and practical review considerations for disease awareness and pre-approval communications, including products with existing indications and rare diseases. Explore pre-approval information exchange (PIE), approaches to reviewing materials, and the needs, questions, and considerations that shape the review process.
Track: General Session

Session Chair(s)



Mary Johnson, PhD, RAC

Consultant
StratPhD LLC, United States

Mary Raber Johnson, PhD, RAC, is founder of StratPhD, a consultancy providing regulatory and medical strategy & writing expertise to pharmaceutical organizations. She has nearly 20 years of experience spanning agency, consulting, and academia, she has supported commercial, medical affairs, publications, and market access agencies across the product lifecycle. She earned her RAC in 2012 and has maintained the credential since. From 2017–2024, she was an Assistant Professor–Clinical and lead faculty of the Regulatory Affairs specialization in the Master of Clinical Research program at The Ohio State University, teaching graduate courses in areas such as regulatory strategy, clinical trial reporting, and global regulations.

10:10 AM — 10:45 AM

Networking Break

10:45 AM — 12:00 PM

Session 7: Connecting with Patients: Improving DTC Communications Through Health Literacy and Engagement

Explore direct-to-consumer and patient communications, including labeling development, content creation, and considerations for the end-user experience. Hear industry and advertising agency perspectives on collaboration and communication throughout the development and review process.

This session explores how health literacy and the patient voice can guide clear, meaningful communication, including during the development of product labeling. Participants will learn practical ways to make health communications clearer, more accessible, and easier to act on. Keeping patients' needs and perspectives at the center can support more confident, well-informed decisions

Learning Objective : At the conclusion of this session, participants should be able to:

- Identify at least three health literacy principles that support clear, accessible, actionable health information.
- Describe two ways to incorporate the patient voice when developing patient-facing communications, including product labeling.
- Assess communications or product labeling for clarity and alignment with patient needs, using different tools described.

Track: General Session

Session Chair(s)



Kristen Heinlein, PharmD

Vice President, Advertising & Promotion Regulatory
Takeda, United States

Kristen Heinlein has almost 20 years' experience in pharmaceutical industry, having spent the past 12 years in various leadership roles in Advertising & Promotion Regulatory. She is currently Vice President, U.S. Advertising & Promotion Regulatory, supporting the U.S. Business Unit portfolio at Takeda. Prior to joining the Regulatory team, Kristen held various positions of increasing responsibility in Medical Communications at Shire, which also included an international assignment. Preceding her time in industry, Kristen was a Clinical/Staff Pharmacist at Peninsula Regional Medical Center in Salisbury, MD.

12:00 PM — 1:00 PM

Lunch Roundtable Discussions

12:00 PM — 1:00 PM

Networking Luncheon

1:00 PM — 2:15 PM

Session 8: Maximizing Digital Engagement While Navigating Promotional Compliance

Pharmaceutical companies are communicating across an expanding mix of channels and voices from influencers, KOLs, and patient ambassadors. These communications can raise complex questions about when content may be considered promotional, what requires review, and how to maintain appropriate oversight across channels. This session will explore

practical approaches for assessing digital and social media communications, addressing emerging platforms and coordinating review across functions while supporting consistent, compliant engagement.

Track: General Session

Session Chair(s)



Heta Zaveri, PharmD, MBA

Regulatory AdPromo Practice Leader
Opus Regulatory, United States

Heta Zaveri is a Practice Leader for the Opus Regulatory Advertising and Promotion team, bringing over 15 years of experience in Regulatory AdPromo and Medical Review. She partners with pharmaceutical organizations to navigate complex promotional regulations and deliver compliant, strategic solutions. Heta earned her Doctor of Pharmacy (PharmD) and Master of Business Administration (MBA) from Drake University, combining clinical expertise with business insight to support effective, compliant promotional strategy.

Speaker(s)



Speaker

Representative Invited

Takeda Pharmaceuticals, United States



Speaker

Representative Invited

Opus Regulatory, United States



Speaker

Representative Invited

EMD Serono , United States

2:15 PM — 3:30 PM

Session 9: Putting AI into Practice: Improving Efficiency and Effectiveness in Advertising and Promotion

Explore how artificial intelligence is being incorporated into advertising and promotion activities, from implementation to practical day-to-day use. Compare applications and options available to small and large companies across industry.

Track: General Session

Session Chair(s)



Janet Gottlieb, PhD

Head of Medical Review Solutions
Canopy Life Sciences, United States

Dr. Janet Gottlieb's experience in research, diagnostics, medical devices, and pharmaceuticals in a career spanning over two decades provides critical insight into medical review. She is adept in the formation, expansion, and training of centralized Medical Promotional Review teams, resulting in greater efficiencies via improved turnaround times, consistency in guidance, enhanced communication, and successful commercial launches. She is a recognized subject matter expert in the field, presenting as an invited speaker at multiple industry conferences. Dr. Gottlieb holds an undergraduate degree in Biological Sciences and Ph.D. in Medical Microbiology and Molecular Virology from the University of California, Irvine.

3:30 PM — 3:45 PM

Closing Remarks

3:45 PM — 3:45 PM

Conference Adjourns