Bethesda North Marriott Hotel and Conference Center

Feb 23, 2026 7:00 AM - Feb 24, 2026 3:00 PM

5701 Marinelli Road, North Bethesda, MD 20852

Advertising and Promotion Regulatory Affairs Conference

Advancing Advertising and Promotion in the Age of Innovation

REGISTER →

Print Agenda

Day 1 Feb 23, 2026

7:15 AM — 5:25 PM

Meeting Registration

7:15 AM — 8:00 AM White Oak (Lower Level)

Networking Breakfast

8:00 AM — 8:15 AM

Welcome and Opening Remarks

8:15 AM — 9:00 AM

Session 1: Inside the Agencies: Perspectives on Promotion, Compliance, and Consumer Protection

This session will share insights into current priorities, enforcement trends, and evolving standards impacting prescription drug promotion and advertising. Speakers will highlight how each organization approaches claim substantiation, consumer protection, and industry accountability within an increasingly scrutinized marketplace. The discussion will also address how FTC and NAD activities intersect with FDA-regulated promotion and what companies can do to align their compliance and advertising practices accordingly. Attendees will gain actionable strategies to anticipate enforcement focus areas and strengthen internal review and risk management processes.
Learning Objective :

- Identify three emerging regulatory or enforcement priorities discussed by various agencies, and summarize their impact on prescription drug advertising and promotion practices
- Compare the differing approaches and areas of overlap among the four agencies
- Evaluate how interagency coordination influences enforcement outcomes and apply this understanding to refine risk assessment and escalation processes within attendees' organizations

Track: General Session

Session Chair(s)

Twyla Mosey, PHARMD, RPH

Division Director
FDA, United States

Twyla Mosey is the Division Director of the Division of Advertising and Promotion Review II in the Office of Prescription Drug Promotion at the Food and Drug Administration. She supports the mission of protecting the public health by overseeing Division correspondences and is responsible for critical decision-making, strategic planning and all Division activities. Over the past 15 years, Twyla has held various roles within the Agency and pharmaceutical industry. She received her Doctor of Pharmacy degree from Florida Agricultural and Mechanical University College of Pharmacy and Pharmaceutical Sciences.

Micheline Awad, MBA

Sr. Director, Regulatory Advertising, Promotion, and Labeling
Day One Biopharmaceuticals, United States

Micheline leads the Advertising & Promotion and Labeling functions at Day One Biopharmaceuticals. Her experience includes Regulatory Affairs Strategy, Advertising & Promotion, and Labeling for Biologics, Drugs, and Devices. Her expertise in product launches is driven by

strategic planning, risk assessment, and maintaining regulatory compliance while fostering innovation and growth. She is passionate about collaborating with cross-functional partners to drive successful product launches while ensuring adherence to complex regulations and guidances. She received her MBA from University of Southern California with a focus on Strategy and Marketing, and her BS in Biology specializing in Biotechnology from George Mason University.

Speaker(s)

Speaker

Phyllis Marcus, JD

Vice President, National Advertising Division
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.

9:05 AM — 10:05 AM

Session [LF11.1]2: Navigating Advertising and Promotion: Multi-Center Updates from FDA

Gain firsthand insights from FDA experts on compliance priorities and best practices shaping the future of compliant advertising and promotion.
Learning Objective : At the conclusion of this session, participants should be able to:

- Identify current compliance priorities in advertising and promotion and explain how these priorities apply across different FDA-regulated product categories
- Analyze recent compliance actions and extract key lessons learned to achieve regulatory compliance
- Describe and implement strategies for continued compliance across FDA-regulated products

Track: General Session

Session Chair(s)

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various roles within the Agency and pharmaceutical industry. She received her Doctor of Pharmacy degree from Florida Agricultural and Mechanical University College of Pharmacy and Pharmaceutical Sciences.

Speaker(s)

Speaker

Kristine T. Khuc, PHARMD

Consumer Safety Officer, CBER
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

Christopher M. Loss, DVM

Supervisory Veterinary Medical Officer (Branch Chief)
FDA, United States

Dr. Loss is a veterinarian and is a Branch Chief in the Division of Pharmacovigilance and Surveillance in the Office of Surveillance and Compliance at the Center for Veterinary Medicine at FDA. He leads and manages a group of veterinarians that evaluate post-market adverse drug event reports, promotion and advertising, and labeling for approved animal drugs, as well as post-market adverse events for some intentionally genetically altered animals.

Speaker

Deborah Wolf, JD

Regulatory Counsel, OPEQ , Regulatory Policy, CDRH
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.

10:05 AM — 10:50 AM

Refreshments, Exhibits, and Networking Break

10:10 AM — 10:40 AM

Sponsored Session/Non-CE: Case Study Spotlight hosted by Vodori & QuidelOrtho Building the Foundation for Innovation: How QuidelOrtho Modernized its MLR Process and Achieved a Review Duration of 6.7 Days

Building the foundation for innovation: How QuidelOrtho modernized its MLR process and achieved a review duration of 6.7 days

As promotional content volume and complexity increase, regulatory and promotional review teams are rethinking how to maintain speed, quality, and compliance. In this session, Vodori and QuidelOrtho share how a structured, data-driven approach to MLR process optimization led to measurable improvements in review efficiency and collaboration without compromising regulatory standards.

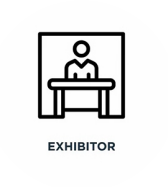
Attendees will hear how QuidelOrtho leveraged benchmarking insights and continuous process enhancements to reduce their average review duration to 6.7 days—nearly a full day faster than benchmark—while improving decision-making consistency across review committees. The discussion will also highlight practical lessons in balancing innovation with oversight, including how to strengthen data governance, enhance reviewer alignment, and implement meaningful process metrics.

Featured Topics

- •Identify which process metrics most strongly correlate with faster, higher-quality MLR outcomes.
- •Apply continuous improvement techniques to enhance collaboration while maintaining compliance.
- •Establish frameworks that enable sustainable innovation and improvement in promotional review.

Track: Hosted Session

Session Chair(s)



Sponsored Sessions

United States

10:50 AM — 12:05 PM

Session 3: DTC Promotion at a Crossroads: The Evolving Landscape of Regulatory and Legal Policy

This session will explore the shifting legal and regulatory landscape shaping prescription drug promotion in today's highly scrutinized environment. Experts will discuss the impacts of government priorities, evolving DOJ expectations, and recent changes in the OPDP/APLB advisory process for DTC advertising. Attendees will gain practical insights into how these developments are redefining risk, compliance, and strategy across the promotional review space.
Learning Objective :

- Identify legal or regulatory developments influencing prescription drug promotion and explain their implications for promotional review practices
- Evaluate how government enforcement trends and policy changes affect DTC advertising, risk assessment, and claim substantiation strategies
- Apply insights to update or refine internal promotional review or monitoring process demonstrating measurable improvement in efficiency and regulatory alignment

Session Chair(s)

Micheline Awad, MBA

Sr. Director, Regulatory Advertising, Promotion, and Labeling
Day One Biopharmaceuticals, United States

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Virginia Foley

Founder, CEO
Compliance Forward, United States

Virginia Foley is the Founder and CEO of Compliance Forward, LLC, where she helps life-science companies navigate the intersection of compliance and innovation. A recognized thought leader and frequent speaker at industry forums, she brings over 20 years of Regulatory Advertising and Promotion experience from a variety of different pharma/biotech companies. She is a pioneer in the application of Large Language Models (LLMs) in Regulatory affairs. Besides being a Regulatory Ad Promo expert, her work style is grounded in creativity, strategic problem solving, and being natural leader and collaborator. Virginia lives in beautiful Northport, Michigan, where she enjoys being active outdoors year-round with her family and loyal Lab retriever.

Speaker(s)

Speaker

Heather Banuelos, JD

Counsel
King & Spalding LLP, United States

Heather Bañuelos is Counsel in King & Spalding's FDA & Life Sciences practice group. She advises clients on regulatory strategies and initiatives for the labeling, promotion, and advertising of FDA-regulated products, as well as non-promotional communications, with particular focus on prescription drugs. She routinely serves on promotional review committees and medical/scientific review committees, providing practical and

insightful advice and recommendations. Heather has over 25 years of experience in food and drug law, including as a former Associate Chief Counsel in FDA's Office of the Chief Counsel and as senior in-house regulatory counsel for Fortune 500 pharmaceutical companies.

Speaker

Alexander Gaffney, MS, RAC

Vice President, Regulatory Policy And Intelligence
AgencyIQ by POLITICO, United States

Alexander Gaffney is a regulatory and media executive responsible for founding and leading the research division of AgencyIQ, the regulatory analysis division of the media company POLITICO. As the Vice President of Regulatory Policy and Intelligence, Alexander directs the division's analysis of regulatory issues affecting pharmaceutical, biotechnology, medical device, chemical and food companies. Before joining AgencyIQ, Alexander analyzed life sciences regulations as part of PricewaterhouseCoopers's Health Research Institute and was the Manager of Regulatory Intelligence at the Regulatory Affairs Professionals Society (RAPS), where he also served as Managing Editor for the company's flagship publication, Regulatory Focus.

12:05 PM — 1:05 PM

Luncheon, Exhibits, and Networking Break

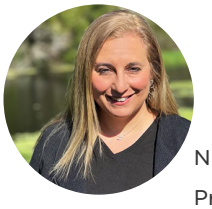
1:05 PM — 2:20 PM

Session 4: Innovation Meets Oversight: AI's Role in Content Creation and Promotional Review

As artificial intelligence continues to evolve and rapidly expands, regulatory reviewers require new tools to evaluate AI technologies to identify regulatory compliance risks. The session will explore the benefits and risks of using generative AI for prescription drug marketing and how marketers can implement guardrails to protect HCP and consumer perceptions of their products, ensure user privacy, and configure generative AI systems to prevent non-compliant presentations of medical information. In addition, the panel will discuss the common regulatory risks presented by AI models including training bias, application of knowledge concepts, and personas. The panel will propose a structured methodology for regulatory reviewers to assess regulatory compliance risks and appropriateness of a given AI model or solution for prescription drug marketing.
Learning Objective :

- Identify the major challenges and risks presented by Artificial Intelligence in advertising and promotion
- Discuss strategies to mitigate risks to presented by AI model hallucinations and bias
- Evaluate new tools to determine if AI models are fit for purpose
- Identify solutions and mitigation strategies to apply guardrails to real-time generative technologies

Session Chair(s)



Nicol George, PHARMD, RPH

Vice President US Regulatory Affairs
Galderma, United States

Nicol George, Pharm.D., is Vice President, US Regulatory Affairs at Galderma. She was previously at Propharma (previously OneSource Regulatory) where she managed the Regulatory & Medical Review staff, provided executive level consulting services including leadership mentoring, process improvements, electronic review system implementations & Advertising and Promotion Training. Before joining OSR, Nicol was at Baxter Healthcare where she held the position of Director, Global Regulatory Affairs Labeling, Advertising & Promotion & led an international team for 5 years (2012-2017). Nicol has been in the industry for over 25 years with pharma, biologic & device experience in Medical (Med Info & Medical Science Liaison) & Regulatory Affairs.

Virginia Foley

Founder, CEO
Compliance Forward, United States

Virginia Foley is the Founder and CEO of Compliance Forward, LLC, where she helps life-science companies navigate the intersection of compliance and innovation. A recognized thought leader and frequent speaker at industry forums, she brings over 20 years of Regulatory Advertising and Promotion experience from a variety of different pharma/biotech companies. She is a pioneer in the application of Large Language Models (LLMs) in Regulatory affairs. Besides being a Regulatory Ad Promo expert, her work style is grounded in creativity, strategic problem solving, and being natural leader and collaborator. Virginia lives in beautiful Northport, Michigan, where she enjoys being active outdoors year-round with her family and loyal Lab retriever.

Speaker(s)

Regulatory Review in the age of AI

Jason Cober, MPA

Director Regulatory Review, AI, Digital Transformation
ProPharma, United States

Jason Cober is the Director - Regulatory Review, AI, and Digital Transformation at ProPharma Group. He previously led FDA/OPDP's eCTD implementation and has 17 years' experience with the Agency's eCTD specification and guidance development process.

Speaker

Yiwen Li

Co-Founder
Solstice Health, United States

2:20 PM — 3:05 PM

Refreshments, Exhibits, and Networking Break

3:05 PM — 4:20 PM

Session 5: Emerging Trends for Leveraging Patient Reported Outcomes (PROs) Inclusion in Labeling and CFL Communications

This session will provide a case study of an Exploratory PRO Inclusion in Oncology Labeling as well as discussion on leveraging CFL to communicate on PROs that may not be in labeling but are consistent with labeling. Finally, we will review recent enforcement relating to PRO promotion.

Learning Objective :

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

- Identify emerging trends in the inclusion of Patient Reported Outcomes (PROs) in product labeling and corresponding CFL communications
- Discuss strategies for communicating PROs in CFL materials that align with labeling, and review recent enforcement actions related to PRO promotion

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)

FDA's Proactive Inclusion of PRO-CTCAE, an Exploratory Measure, in an Oncology Drug Label, Risk or Opportunity for Industry?

Denise Sanchez, JD, MA, MS

Principal Consultant
Opus Regulatory, United States

Denise has worked in the regulatory space for over 20 years with combined industry, government and law firm experience. Industry roles include Regulatory overview of commercial promotion and practices at Allergan Aesthetics, Ironwood, Celgene, & Cubist. At the law firm Hughes, Hubbard, and Reed, Denise worked on drug off-label promotion & product liability litigation. Denise's federal government tenure was in the public health service as Regulatory Counsel for both CDRH and CBER, FDA and in congressional policy at the National Cancer Institute, NIH.

Denise completed undergraduate & public health graduate studies at Columbia University, biomedical sciences graduate work at Rutgers, & health law study at Georgetown University Law Center.

Speaker

Nada A. Glavan, MPH

Executive Director, Commercial Regulatory Affairs
Eisai US, United States

Nada Glavan is an accomplished regulatory affairs leader with more than 25 years of experience guiding pharmaceutical companies through the complexities of advertising and promotion compliance. Throughout her career, Nada has built a reputation for her ability to bridge the gap between scientific innovation and regulatory requirements, partnering with cross-functional teams to support product launches, lifecycle management, and commercial success. She currently serves as Executive Director, Commercial Regulatory Affairs at Eisai Inc.

Speaker

Ann Lee, PHARMD, RPH

Associate Director, Regulatory Affairs, Advertising and Promotion
Allergan Aesthetics, United States

Ann Lee serves as Associate Director of Regulatory Advertising and Promotion at Allergan Aesthetics since December 2023. Prior experience includes roles at Allergan, AbbVie, and Regeneron, where Ann contributed first as a postdoctoral fellow in advertising and promotion, regulatory strategy and labeling, and market access and followed in manager and senior manager roles. Notable areas of expertise include social media, partnership in MLRC/PRC functions and negotiation and collaboration across functional areas and therapeutic areas with experience in CNS, immunology, oncology, and medical aesthetics. Ann holds a Doctor of Pharmacy from the Ernest Mario School of Pharmacy.

Speaker

Rohini Sen, PHD, MS

Director, Patient Experience Data & Strategy, HEOR
AbbVie, United States

Rohini Sen, PhD, is a prominent advocate for patient experience data (PED) with over ten years of experience in patient-centered outcomes research, particularly in oncology and rare diseases. As the Director of Patient Centered Outcomes Research (PCOR) Oncology HEOR at AbbVie, she leads cross-functional efforts to integrate patient insights into oncology drug development. Her dedication to prioritizing patients earned her the prestigious AbbVie CAN Impact Award for successfully incorporating PED early in oncology trials.Dr. Sen has a proven history of developing innovative clinical outcome assessments (COAs) that enhance patient engagement and facilitate effective regulatory interactions with agencies like the FDA and EMA.

4:30 PM — 5:30 PM

Session 6: SIUU Who? Best Practices and Limitations

This session will examine the evolution of the FDA's Good Reprint Practice guidances leading up to the finalized 2025 Scientific Information on Unapproved Uses (SIUU) guidance, highlighting both new elements and limitations. Attendees will learn about materials that qualify or do not qualify for dissemination under SIUU and the critical role of the regulatory reviewer in the approval and dissemination processes. An interactive component will allow participants to evaluate SIUU scenarios to reinforce their understanding of the guidance and discuss practical and compliant execution.

Learning Objective :

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

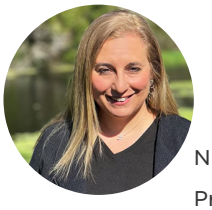
- Assess what types of materials qualify for dissemination under SIUU guidance
- Illustrate the promotional review team's role in review, approval and execution of SIUU dissemination
- Identify regulatory expectations and practical considerations for compliant communication of scientific information on unapproved uses

Session Chair(s)

Alyson Andrikanich, PHARMD

Senior Director, Advertising and Promotion, Regulatory Affairs Americas
Bayer, United States

Alyson Andrikanich is a Senior Director in Regulatory Advertising and Promotion at Bayer Pharmaceuticals. She has over 15 years experience in the pharmaceutical industry, specializing in advertising and promotion in regulatory affairs. Alyson completed a post-doctoral industry fellowship program through Rutgers University and Bayer in Medical Communications/Medical Affairs.



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Vice President US Regulatory Affairs
Galderma, United States

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Speaker(s)

SIUU Who? Best Practices and Limitations of the Scientific Information on Unapproved Uses Guidance

Olivia Estridge, PHARMD

Director
Jazz Pharmaceuticals, United States

Speaker

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.

5:30 PM — 6:30 PM White Oak (Lower Level)

Networking Reception

Day 2 Feb 24, 2026

7:30 AM — 3:25 PM

Meeting Registration

7:30 AM — 8:15 AM White Oak (Lower Level)

Networking Breakfast

8:15 AM — 8:30 AM

Update from Ad Promo Working Group

Update from Ad Promo Working Group

Session Chair(s)

Virginia Foley

Founder, CEO
Compliance Forward, United States

Virginia Foley is the Founder and CEO of Compliance Forward, LLC, where she helps life-science companies navigate the intersection of compliance and innovation. A recognized thought leader and frequent speaker at industry forums, she brings over 20 years of Regulatory Advertising and Promotion experience from a variety of different pharma/biotech companies. She is a pioneer in the application of Large Language Models (LLMs) in Regulatory affairs. Besides being a Regulatory Ad Promo expert, her work style is grounded in creativity, strategic problem solving, and being natural leader and collaborator. Virginia lives in beautiful Northport, Michigan, where she enjoys being active outdoors year-round with her family and loyal Lab retriever.

Melanie Nasuti, MS

Senior Director, Regulatory Affairs
Merck & Co., Inc., United States

Melanie is a Senior Director of Regulatory Affairs at Merck & Co., Inc. in North Wales, Pennsylvania. She oversees the promotional regulatory strategy and the regulatory review, approval, and submission of promotional materials for Merck's oncology products that are co-promoted with other companies. She has over 24 years of industry experience, including roles in Global Medical Affairs, Global Labeling, Global Safety and Clinical Research.

8:30 AM — 9:30 AM

Session 7: Mastering the Art of Promotional Review Committees: Strategies for Success

Unlock the secrets to navigating and excelling in the complex world of Promotional Review Committees (PRCs). This engaging session offers practical insights, proven strategies, and real-world best practices to help participants lead and contribute effectively to PRC discussions. Whether you're new to the process or looking to refine your approach, you'll gain the tools needed to ensure thorough, compliant, and impactful reviews that support strategic decision-making.
Learning Objective :
At the conclusion of this session, participants should be able to:

- Identify the key components and roles within a PRC and understand their significance
- Apply effective strategies to prepare for and participate in PRC meetings, ensuring clear communication and compliance
- Identify practical strategies to build trust, engage in productive dialogue and influence outcomes without relying on formal authority

Session Chair(s)

Anthony Genovese, PHARMD

Group Leader, Regulatory Advertising and Promotion
Johnson & Johnson, United States

Anthony Genovese is the Group Leader, Regulatory Advertising and Promotion at Johnson and Johnson. Prior to joining Johnson & Johnson, he held roles at Bayer Healthcare Pharmaceuticals,

most recently serving as the Director of Regulatory Affairs – Advertising and Promotion and Head of Regulatory Advertising and Promotion Operations. Anthony has over 18 years of pharmaceutical industry experience including roles in medical affairs, external scientific affairs, and regulatory strategy.

Speaker(s)

The Art of Influencing Outcomes Without Formal Authority: Practical Strategies for Regulatory Affairs Leaders

Lynne Bolduc

Founder and Executive Coach
Waverly, United States

Lynne is a Certified Professional Coach and the founder of Waverly, a bespoke executive coaching firm dedicated to the success and wellbeing of legal, regulatory and compliance leaders. She previously practiced law for 20+ years and spent over 15 years in the biotech/pharma industry, including as VP of Legal at Fortune 500 and mid-sized companies. With Waverly, her mission is to help legal, regulatory and compliance leaders transcend their expertise to unlock their leadership potential and impact. Lynne holds an LLB from Université de Montréal and a Graduate Certificate in Healthcare Compliance from George Washington University, and coaching certifications from the ICF, the NeuroLeadership Institute, iPEC and Hogan Assessments.

Speaker

Rebecca Williams

Senior Associate
Ropes & Gray, United States

9:30 AM — 10:15 AM

Refreshments, Exhibits, and Networking Break

10:15 AM — 11:30 AM

Session 8: Navigating Market Access and Payor Engagement Strategies: HCEI and PIE, Oh My!

As the healthcare landscape continues to evolve, timely and effective communication between life sciences companies and key stakeholders is critical to ensure patient access to innovative therapies. This panel will explore the regulatory frameworks and best practices surrounding the use of Real-World Evidence (RWE), Healthcare Economic Information

(HCEI) and Preapproval Information Exchange (PIE) in support of market access strategies. Panelists will discuss how companies can responsibly share product value information with payers and healthcare decision-makers, while remaining compliant. The session will address challenges and opportunities for proactive, compliant engagement across the product lifecycle—from pipeline to post-approval.

Learning Objective :

- Recognize the key types of data supporting payor communications, including RWE and HCEI
- Discuss the current regulatory landscape governing communications with payors
- Guide compliant strategies for engaging payors in the pre-approval period
- Identify recent trends, guidance, and enforcement actions impacting market access communications

Session Chair(s)

Lynn Bowen, PHD

Vice President, Regulatory Affairs Advertising Promotion & Labeling
Alkermes, United States

Lynn Bowen, PhD is currently the Vice President, Regulatory Advertising Promotion & Labeling at Alkermes. Prior to joining Alkermes, she was the Senior Director and US Head of Regulatory Advertising & Promotion at Vertex Pharmaceuticals. Lynn has over 15 years of pharmaceutical industry experience including prior roles in both regulatory and medical affairs. Lynn received her BS in Biotechnology from Rochester Institute of Technology and her PhD in Microbiology from Boston University School of Medicine.

Alyson Andrikanich, PHARMD

Senior Director, Advertising and Promotion, Regulatory Affairs Americas
Bayer, United States

Alyson Andrikanich is a Senior Director in Regulatory Advertising and Promotion at Bayer Pharmaceuticals. She has over 15 years experience in the pharmaceutical industry, specializing in advertising and promotion in regulatory affairs. Alyson completed a post-doctoral industry fellowship program through Rutgers University and Bayer in Medical Communications/Medical Affairs.

Speaker(s)

Speaker

Alan G. Minsk, JD

Partner, Head of Food and Drug Team
Arnall Golden Gregory LLP, United States

Alan Minsk is a partner and chair of the Food & Drug practice at Arnall Golden Gregory LLP, advising pharmaceutical, biologic, medical device, cosmetic, food, and dietary supplement companies on legal and regulatory matters relating to the U.S. Food and Drug Administration. Additionally, Alan counsels life science companies and venture capital firms on regulatory matters involving acquisitions, divestitures, regulatory opinions, co-promotions, and licensing agreements. Recognized nationally and globally by Chambers & Partners for his legal work, Alan is a highly sought-after speaker and author in the life sciences industry. He also serves on a number of advisory boards and regularly conducts training webinars and in-house engagements.

Speaker

Gregory Ringenberg, PHARMD, MS, RPH

Consulting Vice President
ProPharma, United States

11:30 AM — 12:30 PM

Luncheon, Exhibits, and Networking Break

12:30 PM — 1:45 PM

Session 9: Making an Impact, Compliantly, with Digital and Social Media Promotions

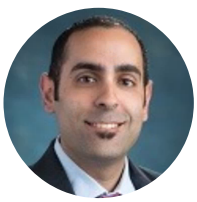
Speaker(s)

Speaker

Melissa Sadowski

Director, US Advertising and Promotion
EMD Serono, United States

Melissa Sadowski is a Director, US Advertising and Promotion in Global Regulatory Affairs at EMD Serono with more than 15 years of pharmaceutical industry experience. She has provided regulatory review and guidance for commercial and developmental products across therapeutic areas and led PRC operations teams.



Speaker

John Paul Marcus, PHARMD

Sr. Director, Commercial Regulatory
Travere Therapeutics, United States

Speaker

Adam Goodcoff, DO

Chief Executive Officer and Co-Founder
MedFluencers, United States

Dr. Adam Goodcoff, CEO of MedFluencers and emergency medicine physician, revolutionized healthcare content during the pandemic, amassing over 800M views and 2M followers. A thought leader named MM+M's 2024 40 Under 40, he elevates healthcare through compliant Digital Opinion Leader campaigns and digital innovation.

1:55 PM — 3:10 PM

Session 10: Telemedicine, Intended Use, and the Art of Staying Compliant

Enforcement activity and use of social media is increasingly shaping how pharmaceutical and medical device companies think about marketing, digital engagement, and third-party relationships. This session examines recent enforcement, marketing trends and regulatory signals that are redefining compliance expectations across pharmaceutical and medical product promotion. Speakers will address how agencies and self-regulatory bodies are approaching emerging areas such as AI-enabled tools, telemedicine, direct-to-patient engagement, and then focus on the growing use of influencers and creators to reach patients, caregivers, and healthcare professionals. Particular attention will be paid to how influencer partnerships introduce unique compliance risks in a highly regulated environment. Panelists will also examine recent actions and guidance from the DOJ, OIG, FDA, the FTC, and the National Advertising Division. This includes how regulators evaluate disclosure practices, company responsibility for influencer statements, and the line between disease awareness and product promotion. The session will conclude with practical takeaways attendees can apply immediately, including insights from BBB National Programs' new influencer certification initiative.
Learning Objective :

- Identify key enforcement trends impacting life sciences marketing and compliance
- Recognize compliance risks in AI, telemedicine, and influencer marketing
- Assess influencer content for disclosures, substantiation, and promotional boundaries
- Apply practical strategies to manage third-party marketing relationships

Session Chair(s)

Darshan Kulkarni, JD, PHARMD, MS

Principal Attorney
Kulkarni Law Firm, PC, United States

Dr. Kulkarni is Principal Attorney for the Kulkarni Law Firm which focuses on providing legal and regulatory solutions to pharmaceutical companies and their providers. He is a pharmacist & lawyer and advises clients on bringing their product to market, focusing on post IND thru commercialization and genericization.

Speaker(s)

Speaker

Katherine Armstrong

Deputy Director, National Advertising Division
BBB National Programs, United States

Katherine Armstrong is a Deputy Director for BBB National Programs' National Advertising Division (NAD). She brings more than 30 years of of consumer protection experience from her tenure at the Federal Trade Commission (FTC), where she served in a variety of roles. In her work as an FTC Attorney Advisor to Chairman Janet Steiger and Commissioner Sheila Anthony, Katherine provided advice on all legal and policy issues related to consumer protection matters before the Commission.Prior to joining BBB National Programs, Katherine spent five years in private practice where she advised clients on privacy and data security matters as well as FTC-related investigations and inquiries.

Speaker

Joanne Hawana, JD, MS

Member
Mintz, Levin, Cohn, Ferris, Glovsky & Popeo P.C., United States

Joanne Hawana is a Member at the law firm of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, practicing in the Health Law/FDA Group and based in the firm's Washington D.C. office. She counsels global clients on the business impact of new U.S. federal and state actions related to drugs, biologics, cellular therapies, foods, and medical devices. Her counseling and compliance support work reaches into all aspects of FDA-regulated companies' operations, both pre-market and post-market, and including enforcement matters. Joanne has a masters degree in molecular genetics from UMDNJ and a bachelors degree in biology from the College of William & Mary. She received her JD from the University of Maryland Francis King Cary School of Law in 2007.

3:10 PM — 3:25 PM

Closing Remarks

3:25 PM — 3:25 PM

Conference Adjourns