Hyatt Regency Bethesda

Feb 24, 2025 7:00 AM - Feb 25, 2025 4:20 PM

One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814-5326

Advertising and Promotion Regulatory Affairs Conference

Advancing Advertising and Promotion in the Age of Innovation

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Print Agenda

Day 1 Feb 24, 2025

7:15 AM — 5:30 PM — Regency Ballroom Foyer

Conference Registration

7:15 AM — 8:15 AM — Regency Ballroom

Networking Breakfast

8:15 AM — 8:30 AM — Regency Ballroom

Welcome and Opening Remarks

8:30 AM — 8:45 AM Regency Ballroom

Update from Ad Promo Working Group

Update from Ad Promo Working Group

Session Chair(s)

Kimberly Belsky, MS

Reg Policy & Intell and AdPromo, Regulatory Affairs
Independent, United States

Kimberly (Kim) Belsky is a seasoned regulatory professional specializing in Regulatory Policy, Intelligence, and Advertising & Promotion (AdPromo). With over 30 years of global experience in the medical product industry, including more than 20 years in regulatory affairs. Her diverse background spans prescription drugs, biologics, over-the-counter products, nutritionals, cosmetics, and medical devices. She also happily co-chairs the DIA AdPromo Working Group within the Regulatory Affairs Community and is actively involved in the Regulatory Affairs Professional Society (RAPS). Kim is passionate about networking, learning, sharing insights and fostering collaboration.

Renee Ambrosio

Executive Director, Office of Promotion and Advertising Review
Merck & Co., Inc., United States

Renee Ambrosio is the Executive Director and Department Head for U.S. Advertising and Promotion, Regulatory Affairs at Merck & Co., Inc. Renee oversees the regulatory review, approval, submission, and promotional regulatory strategy for all U.S. pharmaceuticals and biologic products. Renee has over thirty years of experience across the healthcare spectrum; including 25-years in the pharmaceutical industry, with an emphasis in complex regulatory strategies, overlapping product launches for indications under accelerated approval, as well as sales and marketing, she brings these valuable insights to the industry. Renee is also the current DIA Ad/Promo Working Group Co-Chairperson.

8:45 AM — 9:45 AM Regency Ballroom

Session 1: A Year in Review: Guidance Documents and Enforcement 2024

This session summarizes the Office of Prescription Drug Promotion's (OPDP) enforcement actions, including an overview of all issued letters, with a focus on two oncology-related letters sent to pharma companies. It will also cover recent key policies, including the misinformation guidance and the CCN rule, emphasizing compliance risks and First Amendment considerations related to the SIUU (Scientific Information for Unsolicited Requests) guidance.

Learning Objective :

- Identify the FDA's approach to advertising and promotion enforcement
- Apply lessons learned from recent enforcement actions to current advertising and promotion review
- Recognize the compliance risks and First Amendment considerations associated with SIUU communications

Track: General Session

Session Chair(s)

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)

New Guidance and Enforcement Action for 2024

Lisa Hubbard, RPh, RAC

Principal Consultant, Regulatory Advertising and Promotion
Opus Regulatory, Inc., United States

Lisa Hubbard assists pharmaceutical firms with promotional compliance and related clinical trial considerations at Opus. Her prior roles included Director, Advertising and Promotional Compliance at Alexion and Senior Regulatory and Medical Consultant at One Source Regulatory. Lisa spent 15 years at FDA's Office of Prescription Drug Promotion. She served as Deputy Director, Division of Advertising and Promotional Review 1 from 2012 to 2021. Her role involved reviews in various data rich therapeutic areas, as well as divisional decisions related to compliance, tv ads, and complicated consistent with labeling issues. She contributed to guidance development and co-led First Amendment initiatives. Lisa spent a total of 25 years at FDA.

New Guidance and Enforcement Action for 2024

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.

9:45 AM — 10:30 AM Regency Ballroom

Refreshments, Exhibits, and Networking Break

10:30 AM — 11:45 AM Regency Ballroom

Session 2: Insights from Industry on the Implementation of FDA Policies and Regulations

This session will provide further FDA insight into policies and regulations and allow for an interactive discussion between FDA and industry on best practices and tools for implementation.

Building on the discussion from Session 1, this session will further explore key FDA policies and regulations that have shaped the industry over the past year. With a focus on best practices and implementation strategies, the session will provide an interactive forum for industry professionals to discuss challenges, share insights, and explore practical approaches to compliance.

Learning Objective :

- Interpret FDA policies and regulations to help develop compliant prescription drug advertising and promotion
- Discuss key takeaways and learnings regarding the future of social media, the CCN Final Rule and compliance activities
- Identify common pitfalls with prescription drug promotion and discuss tools and strategies to address them

Track: General Session

Session Chair(s)

Nicol Lorraine George, PharmD, RPh

Vice President, Promotional Review & Labeling Services
ProPharma Group, United States

Nicol George, Pharm.D., R.Ph., is the Vice President, Promotional Review Services & Labeling at OneSource Regulatory (OSR) a ProPharma Group Company, where she manages the Regulatory & Medical Review staff, provides 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 20 years with pharma, biologic & device experience in Medical (Med Info & Medical Science Liaison) & Regulatory Affairs.

Speaker(s)

Insights from the Industry on Implementation – Policies and Regulations

Lisa Hubbard, RPh, RAC

Principal Consultant, Regulatory Advertising and Promotion
Opus Regulatory, Inc., United States

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Insights from the Industry on Implementation – Policies and Regulations

Josephine Secnik, MBA, MS

Executive Director – Product Communications Regulatory Affairs
Eli Lilly and Company, United States

Jo Secnik joined Lilly in 1990 where her career has included assignments in Biopharmaceutical Development, Quality Assurance and Regulatory Affairs. Her experience in Regulatory includes 10 years in global CMC and for the last 14 years supporting the US business on advertising and promotion for marketed products.

11:45 AM — 12:45 PM Regency Ballroom

Networking Luncheon and Roundtable Discussions

12:45 PM — 2:00 PM Regency Ballroom

Session 3: Evolution of DTC Promotion

This engaging session will explore the dynamic landscape of direct-to-consumer (DTC) promotion, highlighting current trends and future implications. Industry experts will provide insights into the evolving DTC strategies, particularly in response to regulatory changes and technological advances.

Learning Objective :

- Examine the digital transformation in DTC strategies, including social media advertising
- Evaluate the complexities in assessment of CFL claims for consumer audiences
- Apply best practices related to broadcast ads and identify broadcast-like technologies where similar principles may apply

Track: General Session

Session Chair(s)

Anthony Genovese, PharmD

Group Leader, Regulatory Advertising and Promotion
Johnson and 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 15 years of pharmaceutical industry experience including roles in medical affairs, external scientific affairs, and regulatory strategy.

Lynn Bowen, PhD

Vice President, Regulatory Affairs Advertising Promotion & Labeling
Alkermes, Inc., 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.

Speaker(s)

Evolution of DTC Strategies: Rise of Social Media

Shruti Gadhia, PharmD

Senior Director, Head of Regulatory Affairs Advertising and Promotion Compliance

Kyowa Kirin, United States

Shruti Gadhia, PharmD, is currently the Senior Director, Head of Regulatory Affairs Advertising and Promotion Compliance, at Kyowa Kirin, where she provides guidance to ensure promotional and nonpromotional materials adhere to FDA regulations and company requirements. Prior to joining Kyowa Kirin, she held roles at Bayer HealthCare Pharmaceuticals and Merck. She has more than 15 years of pharmaceutical experience, including roles in both regulatory and medical affairs. She received her Doctor of Pharmacy from the Ernest Mario School of Pharmacy at Rutgers University.

CFL for Consumers

Torrey Cope, JD

Partner
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. He was also named a “Rising Star” for Life Sciences in LMG's 2017 and 2018 Expert Guides.

Best Practices for Broadcast Ads in the CCN Era

Timothy Candy, PharmD, MS

RA Consultant
Opus Regulatory Inc, United States

Tim Candy is a Principal Consultant for Opus Regulatory, Inc. Following pharmacy school and post-graduate residencies, he has dedicated his career to the pharmaceutical industry since 2005, serving in multiple functional areas of increasing responsibilities, including Medical Affairs, Clinical Affairs, and mostly Regulatory Affairs, supporting a variety of drugs, biologics, medical devices, vaccines, and biosimilars, across a wide array of disease states and at all stages of a product’s lifecycle. Prior to joining Opus in 2017, Tim worked in corporate headquarters locations in the northern Illinois area for TAP Pharmaceuticals, Baxter, Hospira (acquired by Pfizer), and Baxalta (acquired by Shire).

2:10 PM — 3:25 PM Regency Ballroom

Session 4: Medical and Scientific Communication: Examining Recent Developments and Maintaining the Distinction from Promotion

This session will examine recent developments in the area of medical and scientific communications, specifically the FDA’s recent draft guidance documents covering 1) communications to health care professionals regarding scientific information

on unapproved uses and 2) addressing misinformation found in internet-based communications. Additionally, the session will explore the not always straightforward task of distinguishing and separating medical and scientific communications from advertising and promotion, including the functions involved in each and the often blurry line between factual scientific information and product claims. As part of the discussion, panel members will examine ways companies can compliantly and effectively engage in legitimate medical and scientific communication.

Learning Objective :

- Explain the key principles outlined in the FDA's recent draft guidance documents relevant to medical and scientific communications
- Differentiate between medical and scientific communications on the one hand and product promotion on the other
- Apply the aforementioned learnings within their respective organizations to help develop compliant medical and scientific communications

Track: General Session

Session Chair(s)

Mark Gaydos

Head of Labeling and Advertising & Promotion, Global Regulatory Science
Moderna, United States

Mark most recently served as Global Head of Advertising & Promotion within Sanofi's Global Regulatory Affairs organization, with responsibility spanning the General Medicine, Specialty Care, and Vaccine portfolios. In this role, Mark was accountable for regulatory leadership and strategy in supporting impactful product promotion and maintaining strict regulatory compliance in the interest of promoting and protecting patient health. During more than 30 years in industry, Mark has held leadership roles across numerous therapeutic areas, including responsibility for regulatory strategies across the product lifecycle.

Speaker(s)

FINAL Guidance: Updates from FDA on SIUU

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.

Addressing Misinformation About Medical Devices and Prescription Drugs Draft Guidance

Gina L. 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.

(Some) Non-FDA Issues to Consider with Product Promotion

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. He advises pharmaceutical, biologic, medical device, cosmetic, food and dietary supplement companies on legal and regulatory matters relating to the U.S. Food and Drug Administration. He serves on the advisory board for the Food and Drug Law Institute's Food and Drug Law Journal (FDLI) and speaks frequently at conferences, conducts training webinars and in-house engagements. He advises life science companies and venture capital firms on regulatory matters involving acquisitions, divestitures, regulatory opinions, co-promotions and licensing agreements. Alan is recognized by Chambers & Partners "Who's Who Legal, and Best Lawyers."

3:25 PM — 4:00 PM Regency Ballroom

Refreshments, Exhibits, and Networking Break

4:00 PM — 5:30 PM Regency Ballroom

Session 5: AI in Ad Promo: Transforming Marketing While Navigating Compliance

Discover the future of advertising as AI reshapes consumer engagement. In this session, we'll dive into the power of Machine Learning, Large Language Models, and Generative AI to create dynamic, data-driven content that captivates audiences and drives brand loyalty. Uncover how marketing teams are transforming their strategies, building trust, and meeting industry standards with unprecedented speed and precision. Plus, learn how brands are leveraging a strong digital presence to shape their narrative across platforms—and how cutting-edge AI tools are combating misinformation to safeguard message accuracy and brand reputation.

Learning Objective :

- Demonstrate a deeper understanding of artificial intelligence and its impact on Advertising and Promotion
- Recognize how and why marketing teams need to use AI
- Explain the unique obligations and requirements when using GenAI to engage with consumers and HCPs

Track: General Session

Session Chair(s)

Georgina Lee, PharmD

Executive Director, Regulatory Advertising and Promotion
Sage Therapeutics, United States

Georgina Lee is currently the Head of Regulatory Advertising and Promotion at Sage Therapeutics. She has over 10 years of experience in the industry specializing in advertising and promotion, labeling development, and MLR operations. She received her Pharm.D. from the University of Southern California and is the co-chair of the DIA Advertising and Promotion Committee this year.

Virginia Foley

VP Regulatory, Life Sciences & Healthcare
Constellation, Inc., United States

Virginia joined Constellation, Inc., a NYC-based, SaaS/AI company as VP of Regulatory Affairs in early 2024 to lead the compliance efforts for their Life Sciences vertical. Before joining Constellation, her 25-year tenure in Regulatory Affairs Ad Promo spanned positions at various pharmaceutical and biotech companies across the U.S. Prior to joining Constellation, she headed up a team of >40 ad promo consultants at Regulatory firm. Besides being a Regulatory Ad Promo expert, her work style is founded in being a creative thinker, strategic problem solver and being a natural leader and collaborator. Virginia lives in beautiful Northport, Michigan with her family and lab retriever where they enjoy spending time outside in all seasons.

Zoe Dunn

President & CEO
Hale Advisors, Inc., United States

Zoe Dunn, President & CEO of Hale Advisors, is a digital marketing and communications specialist with 20+ years of experience in life sciences industries, driving results for clients' business with multi-channel strategies. Zoe has worked with most of the top 25 Pharmaceutical and Biotech companies and regularly speaks at pharmaceutical and healthcare conferences about Marketing Governance including Omnichannel,

Modular Content and Artificial Intelligence programs for Pharma. Hale Advisors specializes in marketing governance and upskilling solutions.

Speaker(s)

AL Considerations – Legal Perspective

Dara S. Katcher Levy, JD

Director
Hyman Phelps & McNamara P.C., United States

Dara Levy helps pharmaceutical and medical device companies on a wide range of issues relating to product communications. Dara assists clients with products in all stages of development to design engaging communications compliant with FDA legal and regulatory requirements. In the pre-marketing stage, Dara works with companies to strategically communicate with investors, potential marketing partners, and the scientific community, as well as implement effective disease awareness initiatives. At launch and in the post-marketing stage, Dara works closely with corporate communications and marketing to help achieve their goals. Dara serves as the legal reviewer on promotional review committees and conducts company training programs.

A Tale of Three Rhymes

Nazeer Ahmed, MS

Associate Director (acting) for MLRC
Allergan, United States

Nazeer leads gen AI product development at Allergan's MLRC (Medical, Legal, Regulatory and Compliance). Six of his 20 years in the tech industry was in five AI types: rule-based, machine learning, deep learning, gen AI and agentic. Notably, he launched Arabic as Amazon Alexa's 9th language and has applied similar AI (NLP) techniques in regulatory reviews at Allergan. Beyond Allergan, Nazeer serves on advisory panels for various organizations (non-profits and for-profits), guiding them in building their data and AI infrastructure. He also is a gen AI instructor for product managers at Interview Kickstart.

Panel Presentation

Vera Kutsenko

CEO
Artrix Ai, United States

Vera Kutsenko is the CEO at Atrix AI. Atrix works with pharma and med device companies to help turn messy data into clear, confident decisions -- because insights and automations (about MLR or otherwise) are useless if you can't act on them. She has over a decade of experience in software having previously worked as an engineer at Facebook and Uber. She holds a BS and MEng from Cornell in Computer Science and has co-authored a paper on distributed networking.

Speaker

Georgia Gayle, MBA, PMP

Director, Head of Promotional Review and Operations (PRO)
Alexion, Astrazeneca Rare Disease, United States

Georgia Gayle serves as the Director and Head of Promotional Review and Operations at Alexion, AstraZeneca Rare Disease. With a dedication to enhancing patient outcomes, Georgia spearheads the evolution of promotional review procedures, ensuring compliance, operational excellence, and innovation. Georgia cultivates a culture of collaboration across various departments including marketing, medical, legal, and regulatory teams to create impactful communications prioritizing patient safety. Leveraging AI and analytics, she optimizes efficiency while developing strategies that harmonize industry standards with patient needs in mind. Her leadership is instrumental in indirectly supporting the delivery of life-changing therapies in rare disease.

5:15 PM — 6:15 PM | Regency Ballroom

Networking Reception

Day 2 Feb 25, 2025

7:30 AM — 4:00 PM | Regency Ballroom Foyer

Conference Registration

7:30 AM — 8:00 AM | Regency Ballroom

Networking Breakfast

8:00 AM — 9:15 AM | Regency Ballroom

Session 6: Navigating the Complexities of PRC Management

This session will delve into the strategic management of promotional review committees (PRC). We will explore the best practices for ensuring launch readiness, managing post-approval activities, reviewing and approving CFL data, and making informed risk decisions. Additionally, we will discuss effective training strategies, from training project owners on regulatory fundamentals to preparing new regulatory reviewers. At the end of this session, attendees will gain valuable insights to optimize their PRC and drive maximum promotional success.

Learning Objective :

- Identify strategies to streamline the PRC review and approval process for product launches, post-approval activities, CFL data and determining the appropriateness of supporting studies
- Develop effective training programs to equip project owners and regulatory reviewers with the necessary knowledge and skills to ensure compliance and mitigate risks
- Explore frameworks and tools for conducting risk assessment and making informed decisions about the use of CFL data

Track: General Session

Session Chair(s)

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.

Georgina Lee, PharmD

Executive Director, Regulatory Advertising and Promotion
Sage Therapeutics, United States

Georgina Lee is currently the Head of Regulatory Advertising and Promotion at Sage Therapeutics. She has over 10 years of experience in the industry specializing in advertising and promotion, labeling development, and MLR operations. She received her Pharm.D. from the University of Southern California and is the co-chair of the DIA Advertising and Promotion Committee this year.

Speaker(s)

Navigating the Complexities of PRC Management | Module 1: PRC Efficiency

Jan Owen, MPH

Director, MLR Operations Excellence
Sage Therapeutics, United States

I am currently the Director of MLR Operations Excellence for Sage Therapeutics, supporting both medical and promotional reviews in our own internal review programs as well as review programs with a collaboration partner. Having been in this role for three years now, I have led these programs through a number of significant events, included the following: new product launch, label updates, clinical trial data read outs, and a product retirement. We aim to carry learnings and best practices across programs to maximize efficiency and optimize these programs in support of our broad base of stakeholders.

9:20 AM — 10:35 AM Regency Ballroom

Session 7: Disease Awareness Campaigns - Best Practices and What to Avoid

Disease awareness campaigns are essential for informing healthcare professionals (HCPs) and patients. These campaigns highlight disease signs and symptoms, reduce stigma, and encourage proactive health management, enabling timely medical advice. For HCPs, they open dialogue with patients, promote health screenings, and share new insights, especially for rare diseases. This session explores best practices from pre-launch to post-launch, covering media, social channels, and HCP influencer safeguards, focusing on disease education without crossing into treatment promotion.

Learning Objective :

- Discuss best practice recommendations to use disease awareness campaigns leading into anticipated drug approval
- Identify disease awareness education for HCPs and patients versus implied or expressed treatment claims to ensure compliance
- Analyze real-world examples of successful disease awareness HCP Influencer campaigns

Track: General Session

Session Chair(s)

Nicol Lorraine George, PharmD, RPh

Vice President, Promotional Review & Labeling Services
ProPharma Group, United States

Nicol George, Pharm.D., R.Ph., is the Vice President, Promotional Review Services & Labeling at OneSource Regulatory (OSR) a ProPharma Group Company, where she manages the Regulatory & Medical Review staff, provides 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 20 years with pharma, biologic & device experience in Medical (Med Info & Medical Science Liaison) & Regulatory Affairs.

Speaker(s)

Disease Awareness Campaigns: A Regulatory Perspective

Kevin Hollister, MBA, MPH, MS

Head of Advertising and Promotional Compliance
Alexion, United States

Kevin is a seasoned regulatory affairs professional with over 20 years of experience in global medicinal product commercialization. He specializes in optimizing drug promotion through strategic regulatory alignment and is committed to advancing public health. Currently, he leads global advertising and promotion at Alexion and has held key roles at Moderna, GSK, EMD Serono, Cubist, and Amgen. Kevin holds advanced degrees in public health, regulatory affairs, and business administration. He has contributed to several key publications and is active in shaping industry practices through strategic leadership and collaboration with regulatory bodies.

Disease Awareness Campaigns Through an HCP Lens

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.

DSA in Social Media

Joshua Simon, MBA

SVP, Social Center of Excellence
CMI Media Group, United States

Josh Simon leads Centered, CMI Media Group's Social Center of Excellence, as Senior VP. Josh has grown the agency's content and social media services including digital media production, influencer, community management and enterprise guidance. Josh is particularly energized by the emergence of influencer activations within pharma and finding unique ways to minimize content gaps with media plans. Josh has over 14 years of social media experience with 9+ years focused in pharma, in both agency and in house settings.

10:35 AM — 11:15 AM

Regency Ballroom

Refreshments, Exhibits, and Networking Break

11:15 AM — 12:30 PM Regency Ballroom

Session 8: Promoting to Special Populations: Beginning with the End in Mind

As the practice of Medicine becomes more individualized, so must the generation of data to make claims as well as how we reach our special target populations. This session will explore legislative mandates for clinical trial diversity, which will lead to the generation of data for product approval and promotion. We will also explore how patients and generations are evolving in how they seek and digest information and its direct impact on how companies promote to appropriately reach their target audiences, potentially requiring new methods for adequate provision. This session will lead the audience to think more strategically about how to meet our special populations where they are seeking information within the bounds of regulations.

Learning Objective :

- Analyze existing legislation for clinical trial diversity to generate data for promotion
- Evaluate whether we are reaching special populations when and where they are seeking product information
- Assess promotional opportunities and identify alternative methods to provide adequate provision to younger audiences (e.g., QR codes vs. paper)

Track: General Session

Session Chair(s)

Moulakshi Roychowdhury, JD, PharmD

Global Head, Regulatory Affairs, Advertising & Promotion, Allergan Aesthetics
AbbVie, United States

Moulakshi Roychowdhury, PharmD, JD is Global Head of Regulatory Advertising & Promotion at Allergan Aesthetics, an AbbVie Company and leads a team of professionals who advise the company on how to comply with regulations while being competitive & exceeding business goals. She is passionate about finding creative & compliant ways to communicate with customers to optimize their knowledge in making healthcare decisions and believes if intentions are ethical and in support of public health, compliant paths forward must exist. She is dedicated to growing and empowering the next generation of professionals. Moulakshi's favorite saying is by Pablo Picasso: "Learn the rules like a pro, so you can break them like an artist."

Speaker(s)

Promoting to Special Populations: Diversity in Clinical Trials Initiatives

Denise Sanchez, JD, MA, MS

Principal Consultant
Opus Regulatory Inc., United States

Denise has worked in the regulatory space for 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 focused in the public health service, as Regulatory Counsel for CDRH and CBER, FDA and congressional policy at the National Cancer Institute, NIH. Denise completed undergraduate & public health graduate study at Columbia University, biomedical sciences graduate work at Rutgers, & law study at Georgetown University Law Center.

Speaker

Hillary Gurber

Not Provided
Google, United States

Speaker

Jasson W Gilmore

Pharma & Digital Media Executive, Start-up Founder & Adviser
Independent, United States

12:30 PM — 1:30 PM Regency Ballroom

Networking Luncheon and Exhibits

1:30 PM — 2:45 PM Regency Ballroom

Session 9: Ad Promo's Role in Early Cross-Functional Planning

Empower your promotional strategies with compliance at the forefront by integrating AdPromo regulatory insights from the very beginning to support innovative brand planning. In this session, we'll explore how to involve regulatory AdPromo early in the development process from labeling to promotional materials to help transform brand planning and open new doors for impactful, compliant messaging. Join industry experts as they reveal strategies to streamline collaboration between cross-functional teams to avoid roadblocks and boost commercial success. Don't miss this chance to discover how early AdPromo regulatory involvement can turn potential challenges into effective, groundbreaking campaigns that stay ahead of the curve!

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

- Discuss the Benefits of Early AdPromo Regulatory Involvement

- Identify Effective Collaboration Strategies
- Recognize the Full Lifecycle Impact of Compliance

Track: General Session

Session Chair(s)

Zoe Dunn

President & CEO
Hale Advisors, Inc., United States

Zoe Dunn, President & CEO of Hale Advisors, is a digital marketing and communications specialist with 20+ years of experience in life sciences industries, driving results for clients' business with multi-channel strategies. Zoe has worked with most of the top 25 Pharmaceutical and Biotech companies and regularly speaks at pharmaceutical and healthcare conferences about Marketing Governance including Omnichannel, Modular Content and Artificial Intelligence programs for Pharma. Hale Advisors specializes in marketing governance and upskilling solutions.

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)

Chapter 2 – Launch Planning

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.

Chapter 3 - CFL (Consistent with the FDA-Required Labeling)

Josie Waters

DTC Promotion Specialist
DTC Promotion Specialist, United States

With more than 20 years' experience in healthcare and pharmaceutical marketing, Josie is regarded as a strong and compassionate leader. She is a champion of the patient and consistently seeks opportunities to bring forward solutions that can elevate health outcomes. Josie has several novel biologic launches under her belt and has worked across many disease specialties. Her leadership in executing strategies and promotional campaigns has driven impactful results for new products and blockbuster brands. Josie is passionate about collaborating and welcomes diverse thinking to bring the brightest and most meaningful solutions to patients and their families.

2:50 PM — 3:00 PM Regency Ballroom

Closing Remarks

3:00 PM — 3:00 PM

Conference Adjourns