Sheraton Pentagon City Hotel

Mar 12, 2024 7:30 AM - Mar 13, 2024 3:55 PM

900 South Orme Street, Arlington, VA 22204, USA

Advertising and Promotion Regulatory Affairs Conference

Explore the current state of compliance for marketing both biopharmaceuticals and medical devices.

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Print Agenda

Day 1 Mar 05, 2024

11:00 AM — 4:00 PM

Drug and Biologic Ad Promo Primer

Session Chair(s)

Dale Cooke, JD, MA

President

PhillyCooke Consulting , United States

Dale Cooke is president of PhillyCooke Consulting, which helps prescription product marketers use 21st century technology to provide healthcare information while ensuring compliance with FDA regulations written in the 1960s. Dale is the author of Effective Review & Approval of Digital Promotional Tactics, now in its second edition, which was published by the Food & Drug Law Institute.

Day 2 Mar 12, 2024

7:30 AM — 5:30 PM — Main Lobby, outside North/South Ballrooms

Meeting Registration

7:30 AM — 8:30 AM — North Ballroom

Networking Breakfast

8:30 AM — 8:45 AM — South Ballroom

Welcome and Opening Remarks

8:45 AM — 9:30 AM — South Ballroom

Session 1 Keynote: The Future of Prescription Drug Promotion and Digital Marketing: Insights from an Expert Convening

The digital marketing landscape is a dynamic and rapidly evolving ecosystem, and marketers have a rapidly growing array of communication channels to promote products to consumers including social media platforms and podcasts. At the same time, legacy communication channels like television and print ads are integrating new digital features that aim to enhance reach and impact of promotional communications. The U.S. Food and Drug Administration (FDA) is responsible

for ensuring that promotional communications, including direct-to-consumer (DTC) and health care provider (HCP)-directed promotional communications, are truthful, balanced, and accurately communicated. To achieve its mission, it is vital for the FDA to understand the evolving digital marketing landscape, including existing and emerging platforms, strategies, and technologies used by marketers to promote prescription drug products.

A workshop was convened on September 14th, 2023, to explore the current state of and emerging trends in prescription drug promotion in the digital space. Our presentation will provide an overview of themes from the workshop, key emerging trends identified by speakers, and considerations for public health. We will also provide an overview of knowledge gaps highlighted throughout the conversation as well as potential research questions for characterizing emerging trends in this space further.

Learning Objective :

- Identify current and future digital marketing tools and their impact on patient, HCP and consumer perceptions and behaviors
- Evaluate presentation of risk information and disclosures of material information necessary to ensure the advertising or promotion is truthful and non-misleading through digital platforms and technologies
- Recognize emerging trends in digital and legacy marketing channels and what those trends may mean for public health

Track: General Session

Level: Basic

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.

Victoria Gemme, MBA, MS

Policy Research Associate
Duke-Margolis Center For Health Policy, United States

Victoria Gemme is a research associate at the Duke-Margolis Center for Health Policy, where she works on a range of policy topics related to medical product development and regulation. Prior to Duke-Margolis, Victoria worked at the Cystic Fibrosis Foundation where she oversaw a diverse policy portfolio covering basic science research, drug development, antimicrobial resistance, and organ transplant among other topics. Victoria graduated from Vassar College with a Bachelor's degree in neuroscience, from Suffolk University with a Master's in Ethics and Public Policy, and from Quantic School of Business and Technology with a Master's in Business Administration.

Speaker(s)

Keynote

Jason Cober, MPA

Lead Project Manager
OPDP | OMP | CDER | FDA, United States

Jason Cober is the Lead Project Manager in the FDA's Office of Prescription Drug Promotion. He leads OPDP's eCTD outreach efforts and has 15 years experience with the Agency's eCTD specification and guidance development process.

9:30 AM — 10:10 AM North Ballroom

Refreshments, Exhibits, and Networking Break

9:35 AM — 10:05 AM Cavalier A

Sponsored Session/Non-CE: Case Study Spotlight hosted by Hale Advisors: Preparing Promotional Review for the Shift to Omnichannel Marketing

Pharmaceutical and biotechnology companies are shifting from multichannel to omnichannel marketing and modular content to drive better customer experience.

Join omnichannel marketing experts Zoë Dunn and Jason Cober, the Lead Project Manager for the FDA's Office of Prescription Drug Promotion (OPDP), for an interactive discussion to demystify omnichannel and the complexities it introduces to promotional review.

Discover how you can amend your promotional review and OPDP submission processes and prepare review organizations to make a successful transition.

Coffee and a special local treat will be served!

Featured Topics:

- How omnichannel differs from multichannel marketing
- An example of omnichannel marketing in practice
- The industry's current state of omnichannel readiness
- Critical components to support the variable and modular content review process
- 2253 submissions and claims updates

- How to prepare for a conversation with OPDP
- Distinguishing variable content from modular content
- The importance of a traceability matrix

Track: General Session

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Jason Cober, MPA

Lead Project Manager
OPDP | OMP | CDER | FDA, United States

Jason Cober is the Lead Project Manager in the FDA's Office of Prescription Drug Promotion. He leads OPDP's eCTD outreach efforts and has 15 years experience with the Agency's eCTD specification and guidance development process.

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 organizational readiness in multichannel marketing. Hale Advisors specializes in digital governance and competency solutions.

10:10 AM — 10:55 AM South Ballroom

Session 2: FDA Updates – A Busy Year

This session will feature senior representatives from CDER, CBER and CDRH. The group will provide updates on recent FDA advertising and promotion activities, including compliance actions, process modifications, and program highlights.

Learning Objective :

- Apply lessons from recent compliance actions to current advertising and promotion review work
- Recognize significant advertising and labeling concerns that each FDA medical product Center addresses
- Recognize the broad portfolio of FDA's activities involved in regulating medical product promotion

Track: General Session

Session Chair(s)

Catherine Gray, PharmD

Director, Office of Prescription Drug Promotion, OMP, CDER
FDA, United States

Catherine Gray leads the Office of Prescription Drug Promotion (OPDP) at the FDA. Her diverse team of professionals focuses on the challenging and evolving policy and operational issues pertaining to the promotion of prescription drugs. She oversees policy development, social science research, regulatory counseling, compliance activities, labeling recommendations, stakeholder engagement, and operational support to the office as it realizes its mission to protect the public. Her over twenty years of experience include roles in clinical pharmacy and the pharmaceutical industry. Dr. Gray received a B.S. from the University of Notre Dame and a Doctor of Pharmacy from Campbell University and completed several fellowships.

Amy Muhlberg, PhD

Deputy Director, OPDP's Division of Promotion Policy, Research and Operations
FDA, United States

Amy Muhlberg is Deputy Director of the Division of Promotion Policy, Research, and Operations in the Office of Prescription Drug Promotion (OPDP). She joined OPDP in 2021 as a Staff Fellow leading the development of guidance documents, regulations, and citizen petition responses related to prescription drug promotion. She held a similar role in FDA's Office of Policy for Pharmaceutical Quality, working on drug product quality and manufacturing issues across the product lifecycle. She has over two decades of FDA policy experience in trade associations, regulated industry, and on Capitol Hill. Amy earned her Ph.D. in Biochemistry from The Scripps Research Institute, and received her undergraduate degree from McGill University.

Speaker(s)

FDA Updates in Advertising and Promotion: CBER APLB

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, where she is a Consumer Safety Officer 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 as a pharmacist at the Fairfax Health Center and at the Andrew Rader Health Clinic.

Evaluating Labeling and Advertising

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.

11:00 AM — 11:45 AM South Ballroom

Power Learning Session 3: Pharma Marketing and the Role of BBB National Programs' National Advertising Division

Join this session to gain insight into how to uphold industry standards in pharmaceutical advertising from the National Programs' National Advertising Division's (NAD). We will explore a recent case study where the NAD took action to remove misleading drug claims, offering a real-world example of their commitment to consumer protection. Discover how NAD's rigorous examination of pharmaceutical promotions ensures accurate information and safeguards public health. This session is an opportunity to learn about NAD's vital role and how it can be a resource in maintaining transparency and building integrity in the pharmaceutical sector.

Learning Objective :

- Describe BBB National Programs and NAD's role in Pharma promotion
- Compare NAD actions with those of the FDA's OPDP
- Apply newly acquired knowledge with internal stakeholders

Track: General Session

Session Chair(s)

Bob Dean, MBA

Head of Global Labeling Strategy & Ad/Promo
EMD Serono, United States

Bob is currently the Vice President of Commercial Regulatory at Myovant Sciences. Prior to that, he was Director/Team Lead at Merck & Co., Inc. in the Office of Advertising and Promotion Review. Prior to joining Merck, Bob was the Director of the Division of Advertising and Promotional Review 2 in the Office of Prescription Drug Promotion (OPDP). During his 15 years at OPDP, he oversaw core functions within FDA including advisory and labeling reviews, as well as investigations and enforcement actions. He co-developed new FDA Policies,

Regulations and Guidance documents and led the efforts of the educational outreach program (Bad Ad) to help engage stakeholders in the medical community.

Speaker(s)

Pharma Marketing and the role of BBB National Programs' National Advertising Division

Laura Brett

Vice President, National Advertising Division
BBB National Programs, United States

Laura Brett leads the National Advertising Division of BBB National Programs and its New York office. The National Advertising Division (NAD) is the centerpiece of the U.S. advertising industry's system of self-regulation. In over 100 cases each year, the NAD reviews advertising and upholds advertising law standards that are set by the Federal Trade Commission (FTC). Laura speaks regularly on advertising law in the U.S. and internationally and has published articles and been interviewed on emerging issues in advertising law like the use of consumer reviews, influencer marketing, "green" claims, and dark patterns.

11:45 AM — 12:45 PM North Ballroom

Luncheon, Exhibits, and Networking Break

12:45 PM — 2:00 PM South Ballroom

Session 4A: Submitting and Responding to Advertising Complaint Letters: Why, How, and Where?

Advertising and promoting medical products (drugs, biologics, vaccines and medical devices) is a complex area with many competing business considerations, along with a multitude of federal and state laws and regulations. Competition for customers – consumers/patients and health care providers or purchasing organizations – is fierce. What can you do if you see another company making claims for a similar product to your best-seller that may not be wholly truthful? What should you do if you become aware of prescription drug or device promotional campaigns that do not comply with FDA fair balance requirements? If you receive a cease-and-desist letter from a competitor, how do you evaluate whether and how to respond?

While not every potential violation of advertising and promotion laws is actionable through a direct lawsuit, there may be other ways to use non-court forums to handle a potential unfair competition matter or initiate government scrutiny into a competitor's claims. This session will examine the various options for submitting cease-and-desist letters to the competitor company or complaints to the FDA, the Federal Trade Commission, the BBB's National Advertising Division,

and others. Panelists will discuss best practices for decision making on when to submit a complaint as well as preparing and submitting complaints; address what to expect after submitting a complaint in the various fora; and share case studies involving their own experiences with private dispute resolution settings and regulatory agencies. In addition, panelists will consider what to do if you receive a cease-and-desist letter from your competitor.

Learning Objective :

- Determine when to act and submit a cease-and-desist letter to the company or complaint to regulatory agencies
- Describe what to expect after submitting cease-and-desist or complaint letters
- Evaluate your position and options if you receive a cease-and-desist letter related to your advertising/promotional campaign

Track: General Session

Session Chair(s)

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.

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)

FTC vs. FDA – Complaints

Alan G. Minsk, JD

Partner, Head of Food and Drug Team

Arnall Golden Gregory LLP, United States

Alan G. Minsk is a partner in the Food and Drug and Government and Regulatory Practices. Mr. Minsk was recognized in Chambers USA America's Leading Lawyers for Life Sciences, Regulatory/Compliance and was selected for inclusion in the International Who's Who of Life Sciences Lawyers 2013-2018. Mr. Minsk focuses his practice on advising pharmaceutical, biologic, medical device, cosmetic and food companies, on all legal and regulatory matters relating to the U.S. Food and Drug Administration (FDA).

Device and Digital Health-Specific Considerations

M. Jason Brooke, JD, MS

Attorney & Managing Member
Brooke & Associates, United States

M. Jason Brooke, MSE, JD, CSQE is an attorney and the Managing Member at Brooke & Associates—a digital health legal and regulatory advisory firm. Jason offers a unique, multi-disciplinary perspective on the digital health industry as a regulatory attorney, scientist, technologist, and quality consultant, bringing a focused expertise in the medical device industry that combines 20 years of experience ranging from science and technology development to business strategy and operations to legal and regulatory compliance.

12:45 PM — 2:00 PM Cavalier BC

Session 4B: Beginning with the End in Mind: Early Cross-Functional Planning for Promotion

Regulatory Advertising and Promotion has a critical role in early-stage cross-functional development discussions. Deciding on clinical study design and endpoints has significant implications for advertising and promotion once the product is launched. In addition, FDA's Consistent with FDA Labeling Guidance plays a role in these early cross-functional planning discussions.

Learning Objective :

- Identify how early development decisions impact advertising and promotion
- Describe regulatory advertising and promotion's role and value in early cross-functional planning
- Illustrate how the FDA's Consistent with FDA Labeling Guidance can influence decisions on clinical trial design

Track: General Session

Session Chair(s)

Alyson Andrikanich, PharmD

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

Alyson Andrikanich is a Senior Director in Regulatory Advertising and Promotion at Bayer Pharmaceuticals. She has over 14 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.

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.

Speaker(s)

Target Product Profiles and Drug and Device Development

Denise Sanchez, JD, MA, MS

Principal Consultant
Opus Regulatory Inc., United States

Denise has worked in the regulatory space for close to 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.

Effectively Presenting CFL Information in Promotional Communications

Kristen Heinlein, PharmD

VP, US Advertising and 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.

2:00 PM — 2:40 PM North Ballroom

Refreshments, Exhibits, and Networking Break

2:40 PM — 3:25 PM South Ballroom

Power Learning Session 5: Best Practices for Diversity and Inclusion in Medical Product Advertising

Social justice and health equity issues remain center-stage in current national discussions. In the realm of advertising and marketing, research shows that consumers are more likely to trust brands that represent diversity, and that a consumer is likely to lose trust in a brand if they don't see themselves represented in the brand's advertising. However, a recent study across industries showed that the majority (54%) of consumers still don't feel represented in advertising. Pharmaceutical and medical device companies in the US face an additional challenge, as they may aim for inclusivity in their direct-to-consumer advertising but must still accurately represent their products' approved indication and studied populations.

This power learning session aims to provide attendees with a deeper understanding of the concepts of diversity, inclusion, and implicit bias and will explore human diversity that goes beyond physical appearance, such as gender/gender identity, socioeconomic status, religion, sexual orientation, ethnicity, neurodiversity, and physical ability. The presentation will cover compliant integration of these concepts into promotional labeling, including recent examples from the industry. Panelists will also share best practices and offer tips for raising awareness of social issues with content creator colleagues with whom regulatory affairs professionals are working day-to-day.

Learning Objective :

- Analyze risks associated with certain patient depictions in medical product advertising
- Identify viable options for incorporating diverse patient perspectives into product advertising without creating significant regulatory risks for the business
- Evaluate marketing proposals for new ad campaigns with a broader appreciation of how diversity, inclusion, and equity can play a role in medical product branding

Track: General Session

Level: Basic

Session Chair(s)

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.

Speaker(s)

Speakers

Rachel Imam, MBA

Senior Regulatory Specialist
US WorldMeds, United States

Rachel Imam specializes in regulatory affairs for pre-approval and commercialized drug products. She manages product labeling from inception through NDA/BLA approval for drugs, biologics, combination products, and medical devices and has negotiated labeling for five major applications as well as numerous labeling supplements. She serves as the lead regulatory reviewer on the company's Promotional Review Committee (PRC/MLR) and has facilitated several new product launches. Her advertising and promotional review experience is in the areas of hemophilia, oncology, recovery, and central nervous system disorders, among others, and she has unique experience with boxed warning products, combination products, and co-promotion of drug products.

Speaker

Eugenia Blackmon, JD, LLM

Executive Director of Legal and OEC (Office of Ethics and Compliance) EEDI Strat
AbbVie, United States

Attorney & community leader, Eugenia Blackmon, Esq. is a high-functioning professional that values relationships. Prior to joining AbbVie, Eugenia was General Counsel and Compliance Director for UniWorld Group Inc., head quartered in Brooklyn, New York. Before working in advertising law, Eugenia was a Corporate Mergers & Acquisitions Senior Associate for the national office of PriceWaterhouseCoopers in Washington, DC. Upon joining AbbVie, Eugenia expanded her expertise in Digital Marketing and led a digital transformation initiative for Allergan Aesthetics and Women's Health. Now, Eugenia sits within AbbVie Legal & Compliance as Executive Director of EEDI Strategy.

3:30 PM — 4:45 PM

South Ballroom

Session 6: Making Sound SASS Determinations for CFL Communications

Since the 2018 issuance of FDA's guidance on Medical Product Communications that are Consistent with FDA-Required Labeling, we have seen a proliferation of this information being included in prescription drug promotion. The new evidentiary standard, scientifically appropriate and statistically sound (or SASS), defined in the guidance is a flexible standard whose robustness varies with the nature of the information being communicated. While this presents opportunities for sponsors to expand on the data and other analyses used in promotion, it also presents challenges in terms of ensuring the supporting evidence is adequate in each instance, not to mention appropriately contextualized with study design limitations and other relevant disclosures. During this session, we will examine approaches to CFL assessment, the characterization of CFL information in promotion, and lessons learned from FDA's CFL-related enforcement since the guidance was issued.

Learning Objective :

- Describe the SASS standard and the importance of rigorous CFL assessment consistent with the 2018 FDA guidance
- Determine the types of expertise, beyond traditional review committee roles, teams should consider involving in CFL analyses
- Apply learnings from CFL-related FDA enforcement actions that articulate the Agency's areas of concern and focus

Track: General Session

Session Chair(s)

Mark Gaydos

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

Mark is Vice President and 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 is accountable for regulatory leadership and strategy in developing competitive labeling, supporting impactful product promotion and maintaining strict regulatory compliance in the interest of promoting and protecting patient health. During 30 years in industry, Mark has held leadership roles across numerous therapeutic areas, including responsibility for regulatory strategies across the product lifecycle.

Speaker(s)

Speaker

Adam George, PharmD

President and Founder
ANG Regulatory Consulting, United States

Adam is the Founder of ANG Regulatory Consulting, LLC. He has 18 years experience in regulatory affairs and clinical development focused on oncology. He uses his experience working at FDA, and in industry, to assist clients in developing regulatory strategies for product development programs and prepare clients for interactions with regulators. Prior to ANG, he was the Vice President of Regulatory Affairs at PureTech Health and regulatory affairs

therapeutic area head for oncology and respiratory at Teva Pharmaceuticals. At FDA, Adam was a clinical reviewer in the Division of Hematology Products and a senior reviewer in the Office of Prescription Drug Promotion. At OPDP Adam served as the subject matter expert in clinical trials.

Speakers

Kellie B. Combs, JD

Partner
Ropes & Gray LLP, United States

Kellie Combs is a Partner in the Washington, DC office of Ropes and Gray, where she advises pharmaceutical, biotech, and medical device companies on a range of FDA regulatory issues, including promotional compliance, lifecycle management, and regulation of clinical research. She serves as co-counsel to the Medical Information Working Group, represented Pacira in its litigation against FDA, and has extensive experience handling matters implicating FDA promotional rules and the First Amendment.

4:45 PM — 5:45 PM | North Ballroom

Networking Reception

Day 3 Mar 13, 2024

7:00 AM — 4:00 PM | Main Lobby, outside North/South Ballrooms

Meeting Registration

7:00 AM — 8:00 AM | North Ballroom

Networking Breakfast

8:00 AM — 8:30 AM | South Ballroom

Session 7: Recent and Relevant – Insights from the DIA Ad Promo Working Group

Learn and engage! This session will provide an overview of recent hot topics and learnings discussed by DIA's Advertising and Promotion Working Group. Topics include enforcement letter deep dives, Draft and Final Guidance/Rule reviews, basics of Medical Device promotion, OPDP research, webinar highlights, ex-US regulations/guidance (UK, Australia, EU/Medical Device) and more! Learn how you can enhance your knowledge and decision-making throughout the year by joining the AdPromo Working Group.

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

- Gain insights into the evolving AdPromo environment
- Relate learnings to current tactics and enhance decision-making
- Decide to join the DIA AdPromo WG!

Track: General Session

Session Chair(s)

Sorcha McCrohan, MSc

Specialist, Scientific Programs
DIA, United States

Sorcha McCrohan is a Specialist of Scientific Programs for the Americas Region at DIA. In her current role, she focuses on content development and strategy for DIA's meetings to improve and facilitate innovation in clinical research, drug development, and the fields of devices and diagnostics. Before joining DIA, she conducted COVID-19 research in Chiapas, Mexico, and worked in marketing within Pfizer's Global Vaccines Meningococcal franchise. Sorcha holds a BA in Sociology from Mount Holyoke College and an MSc in Global Health, Disease Prevention & Control from Georgetown University.

Speaker(s)

Speaker

Kimberly Belsky, MS

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

Kimberly (Kim) Belsky is a regulatory professional with expertise in Regulatory Policy & Intelligence and AdPromo. With over 30 years of global experience in the medical product industry, including 20+ years in regulatory affairs, Kim's diverse experience including scale up and tech transfer, quality/compliance, advertising & promotion, labeling, and regulatory policy and intelligence. Her background includes Rx drug/biologics, OTCs/Nutritionals/Cosmetics, and medical devices. Kim is the co-chair of the DIA AdPromo WG (part of the RegAffairs Community) and is an active member in RAPS. Kim is passionate about networking, learning, and collaboration.

Speaker

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.

8:35 AM — 9:50 AM South Ballroom

Session 8: Use of Consumer CFL in Promotional Materials

This session will focus on the FDA Guidance for Medical Product Communications that are Consistent with the FDA-Required Labeling (CFL) and how it can be applied to Direct-to-Consumer (DTC) promotional materials. Consumer-facing materials frequently present challenges as the content needs to be truthful, non-misleading, and fairly balanced while being easily understood by the lay audience and consumer. With a focus on DTC materials, we will evaluate the important considerations for incorporating CFL communications into promotional materials and examine trends and best practices across the industry.

Learning Objective :

- Describe how to assess CFL claims in the context of consumer-facing materials based on the FDA Guidance
- Apply learnings to consumer messaging across various platforms and material types
- Identify opportunities to leverage CFL claims in patient-facing materials with appropriate context

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.

Speaker(s)

Speakers

Lynette Hopkinson

Principal
CoRA Consulting LLC, United States

Lyn Hopkinson is a Regulatory Affairs executive with twenty-five years of experience in the pharmaceutical/biotech industry leading global teams previously as Sr Vice President, Regulatory and Quality, Imara; Vice President, Global Regulatory Strategy Cystic Fibrosis and Commercial Regulatory Affairs, Vertex Pharmaceuticals; Sr Director, Commercial Regulatory Affairs, Eisai. As Principal of CoRA Consulting LLC, Lyn leverages her significant experience in Regulatory Advertising and Promotion, Labeling and Clinical Strategy (early and late-stage development, regulatory submission and approval, launch and life-cycle management) to guide and support a broad range of clients across the pharmaceutical and biotechnology industry.

9:50 AM — 10:30 AM North Ballroom

Refreshments, Exhibits, and Networking Break

10:30 AM — 11:30 AM South Ballroom

Session 9: The ABC's of SIUU: Recent FDA Revised Draft Guidance

This session will discuss the FDA's recent revised draft guidance "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers". This guidance addresses stakeholder questions regarding certain communications by firms to health care providers of scientific information on unapproved use(s) of approved/cleared medical products.

Learning Objective :

- Describe the scope and applicability of the SIUU guidance
- Identify the types of SIUU communications
- List the disclosures recommended when disseminating SIUU communications

Track: General Session

Session Chair(s)

Amy Muhlberg, PhD

Deputy Director, OPDP's Division of Promotion Policy, Research and Operations
FDA, United States

Amy Muhlberg is Deputy Director of the Division of Promotion Policy, Research, and Operations in the Office of Prescription Drug Promotion (OPDP). She joined OPDP in 2021 as a Staff Fellow leading the development of guidance documents, regulations, and citizen petition responses related to prescription drug promotion. She held a similar role in FDA's Office of Policy for Pharmaceutical Quality, working on drug product quality and manufacturing issues across the product lifecycle. She has over two decades of FDA policy experience in trade associations, regulated industry, and on Capitol Hill. Amy earned her Ph.D. in Biochemistry from The Scripps Research Institute, and received her undergraduate degree from McGill University.

Catherine Gray, PharmD

Director, Office of Prescription Drug Promotion, OMP, CDER
FDA, United States

Catherine Gray leads the Office of Prescription Drug Promotion (OPDP) at the FDA. Her diverse team of professionals focuses on the challenging and evolving policy and operational issues pertaining to the promotion of prescription drugs. She oversees policy development, social science research, regulatory counseling, compliance activities, labeling recommendations, stakeholder engagement, and operational support to the office as it realizes its mission to protect the public. Her over twenty years of experience include roles in clinical pharmacy and the pharmaceutical industry. Dr. Gray received a B.S. from the University of Notre Dame and a Doctor of Pharmacy from Campbell University and completed several fellowships.

Speaker(s)

Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products

Kathleen David, BSN

Division Director, Division of Promotion Policy, Research, and Operations, OPDP
FDA, United States

Kathleen (Katie) David is the Division Director for the Division of Promotion Policy, Research, and Operations in the Office of Prescription Drug Promotion (OPDP) at the Food and Drug Administration (FDA). Katie joined OPDP in 2012 as a Regulatory Review Officer and has also held the position of Team Leader and Deputy Supervisor for Policy, Research and Operations. Prior to joining FDA, Katie worked in the fields of corporate intelligence and oncology nursing. She has a B.A. in history from Washington University in St. Louis and a BSN from University of Maryland.

Speaker

Shelby Buettner, JD

Assistant General Counsel and Compliance Officer
Becton Dickinson (BD), United States

Shelby has advised pharmaceutical and medical device manufacturers, healthcare and technology companies, hospitals, and healthcare providers on a variety of regulatory and compliance matters. Shelby previously served as

Principal Legal Counsel, Enterprise Legal Regulatory and Acting Lead Counsel, Mechanical Circulatory Support Operating Unit at Medtronic; Associate Chief Counsel at the Food and Drug Administration; and before that, was in private practice. Shelby also has experience coordinating clinical research at an academic medical center and managing biomedical projects funded by the Department of Defense and the National Aeronautics and Space Administration.

11:30 AM — 12:30 PM North Ballroom

Luncheon, Exhibits, and Networking Break

12:30 PM — 1:45 PM South Ballroom

Session 10A: Global Ad Promo and Enforcement Insights

During this session, panelists will provide insights into Regulatory Advertising and Promotional Compliance for pharmaceutical companies doing business outside the US. The presentation on enforcement will comprehensively cover global policies, guidance documents, guidelines, and regulations, exploring industry self-regulation on a global scale. It will delve into the standards applied and how companies support these efforts worldwide, providing insights into the structure of regulatory and review functions. Additionally, the discussion will focus on managing the review of corporate content on global platforms, taking into consideration geographic boundaries and implications for different regions.

The panel will consider perspectives from legal experts, the role of governing bodies like PMCPA in the UK, and delve into challenging-to-find information, such as examples from Health Canada/Canada. The discussion will also touch on avoiding global enforcement through an overarching international review team. This comprehensive overview aims to provide attendees with a nuanced understanding of the intricate landscape of global regulatory advertising and promotional compliance.

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

- Analyze international Regulatory Ad Promo enforcement, with a potential focus on social media trends
- Examine examples from HC/Canada for a deeper understanding
- Discuss strategies for avoiding global enforcement through the establishment of an overarching international review team

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)

Global Review – a Strategic Enterprise Function

Richard Lem, PharmD

Director, International Regulatory Affairs Advertising and Promotion
Abbvie, United States

Richard Lem is the Director of International Regulatory Affairs Advertising and Promotion at Allergan Aesthetics, an AbbVie Company. In this role, he leads a team that provides regulatory guidance on ex-US commercial activities and advises country and area level review teams on compliant promotional activities. Prior to joining Allergan Aesthetics, an AbbVie Company, Richard was Head of Global Regulatory Affairs Advertising and Promotion at TG Therapeutics, where he implemented policies to support the company's transition from a clinical stage to commercial organization and established the Global Regulatory Affairs Advertising and Promotion team to support compliant commercialization activities.

Understand What Promotional Compliance Means for Pharmaceutical Companies Looking to Market their Products in Europe

Audrey Athlani Jorno, PharmD, MS

Associate Director, Promotional Materials & Compliance
Pharmalex, France

Audrey Athlani Jorno is Doctor of Pharmacy with a Master Degree in Regulatory Affairs. She brings more than 10 years of experience in Promotional Materials and Healthcare compliance activities for wide range of products. Working in pharmaceutical and consulting companies provided her an extensive experience in the global evaluation of external communication spanning from corporate documents to the local affiliates' adaptation. Audrey Athlani Jorno has gained experience as project manager and coordinator though many diverse international projects in Promotional materials and Healthcare compliance activities, from the strategy to the operational phases.

Global Compliance: Legal Implications & Best Practices

Anne K. Walsh, JD

Director
Hyman, Phelps & McNamara, PC, United States

With more than 27 years of experience in private practice and government, Ms. Walsh helps pharmaceutical and medical device companies comply with, and defend against, FDA regulation. She regularly counsels clients on managing FDA inspections, and responding to seizure and injunction actions, warning letters, and recalls. She has specific expertise in matters involving health care fraud, off-label promotion, and manufacturing practices, and has investigated and negotiated dozens of matters that have implicated False Claims Act liability and exclusion by the HHS Office of Inspector General.

12:30 PM — 1:45 PM Cavalier BC

Session 10B: The Evolving World of Scientific Exchange

The numerous and varied opportunities for scientific exchange (reactive and proactive) continue to introduce new challenges. This session aims to provide a regulatory background for these types of communications and discuss different examples of scientific exchange that various companies are currently participating in today, for example, medical booth activities, medical affairs activities, non-CME sponsored symposia, and more.

Learning Objective :

- Describe the regulatory basis for scientific exchange
- Evaluate different features of scientific exchange
- Identify the different considerations in review of proactive scientific exchange

Track: General Session

Session Chair(s)

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)

Legal and Regulatory Framework for Scientific Exchange

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 20 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.

Proactive Medical Affairs Communications

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.

1:45 PM — 2:25 PM South Ballroom

Refreshments, Exhibits, and Networking Break

2:25 PM — 3:40 PM South Ballroom

Session 11: Unlocking the Future: Leveraging AI in Promotional Review Processes for Enhanced Compliance and Efficiency

In this session, we will better understand the potential of utilizing AI in the various parts of the promotional review process. The session will include non-promotional case studies to understand existing applications and showcase current AI tools, their applications, industry interests, necessary capabilities, and ideal states for value.

Key topics covered will include best practices for seamlessly integrating new Cplatforms into advertising, addressing internal guidance, consistency, above-brand/BU governance, and SOPs for the exploration of new technology. The session will delve into the effective use of AI as a compliance tool, particularly for tracking changes in digital platforms. Moreover, participants will engage in discussions around creating internal AI tools for promotional review, criteria used, and essential

considerations for a wishlist. The session will conclude by assessing the efficiencies and existing applications of AI tools, with a special focus on the potential utilization of ChatGPT by reviewers.

Learning Objective :

- Examine insights into best practices for incorporating new platforms into advertising
- Determine how AI can be leveraged as a compliance tool
- Discuss criteria for internal AI tools and explore their applications
- Identify potential applications of ChatGPT for promo review

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)

AI 101

Nazeer Ahmed, MS

Sr. Technical Program Manager (Data Science)
Allergan, United States

Nazeer leads the AI product development at Allergan's Data Science and Engineering division, spearheading its evolution into a next-generation AI organization. Six of his 20 years in the tech industry was in all four AI types: rule-based, machine learning, deep learning, and gen AI. Notably, he launched Arabic as Amazon Alexa's 9th language and has applied similar AI (NLP) techniques in regulatory reviews at Allergan, with a publication forthcoming in RAPS journal in early 2024. Beyond Allergan, Nazeer serves on advisory panels for various organizations (non-profits and for-profits), guiding them in building their data infrastructure, unlocking millions in new revenue, and developing AI capabilities.

Reg Considerations for AI

Jia-Huey Huey, PharmD, RPh

Group Leader, Regulatory Advertising and Promotion
Johnson & Johnson Office of Health Care Compliance & Privacy, United States

Jia-Huey Huey is Group Leader of Regulatory Advertising and Promotion, within Health Care Compliance organization at Johnson & Johnson with responsibility for providing regulatory and compliance advice to the

commercial, medical, research and development teams on a wide-range of matters. Jia currently manages a team and have overall responsibility for setting strategic direction and developing and managing a robust regulatory compliance program. Jia is a licensed New Jersey pharmacist with both a Doctor of Pharmacy and a BS in Pharmacy from the Ernest Mario School of Pharmacy at Rutgers University. She is a Certified Compliance and Ethics Professional and holds the Seton Hall Law School Health Care Compliance Certification.

Reg Considerations for AI

Shakshi Kshatriya

Associate Director, Advertising and Promotion
Abbvie, United States

I am an Associate Director at AbbVie, a global biopharmaceutical company, where I lead the US advertising and promotion, digital and corporate communications compliance for the company's products and services. With over eight years of experience in regulatory affairs and compliance management, I have a deep understanding of the complex and dynamic regulatory environment in the pharmaceutical industry, and the ability to ensure alignment between business objectives and regulatory requirements.

Speaker

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.

3:40 PM — 3:55 PM South Ballroom

Closing Remarks

3:55 PM — 3:55 PM

Meeting Adjourns