DIA

Advertising and Promotion Regulatory Affairs Conference

Primer: March 5 | Conference: March 8-10 | Virtual

PROGRAM COMMITTEE CHAIR

Micheline Awad, MBA
Director, Regulatory Affairs, Advertising and Promotion
Neurocrine Biosciences, Inc.

PROGRAM COMMITTEE CO-CHAIR

Kimberly Belsky, MS,
Executive Director Regulatory Policy & Intelligence and Labeling Operations, Mallinckrodt Pharmaceuticals

PROGRAM COMMITTEE

Carla Brooks, MSc, RAC
Senior Director, Regulatory Affairs, Advertising and Promotion
Blueprint Medicines, Corporation

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Virginia Foley
Principal Consultant
Opus Regulatory Inc.

Catherine Gray, PharmD
Acting Director, Office of Prescription Drug Promotion, OMP, CDER
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Vice President, US Advertising & Promotion, Global Regulatory Affairs
Sanofi

Wayne Pines
President, Health Care
APCO Worldwide Inc.

Lucy Rose, MBA
President
Lucy Rose and Associates, LLC.

Overview

DIA's *Advertising and Promotion Regulatory Affairs Conference* explores the current state of compliance for marketing both biopharmaceuticals and medical products. Join thought leaders from industry, legal, public affairs, and government for interactive and compelling discussions that will shape policy and define strategic priorities within the advertising and promotion regulatory space. Representatives across the FDA will provide the latest information on guidance policies, enforcement actions, and future directions of industry hot topics such as pre-approval activities, labeling strategies, and social media tactics.

This conference is geared towards both early- and late-career professionals with content that advances the understanding of current regulatory policies, details the latest strategies for effective patient engagement, and discusses the trends in advertising for biopharmaceuticals and medical products. Attendees will have the opportunity to network with key thought leaders from the FDA, industry, and other regulatory practitioners, while simultaneously discussing the challenges and opportunities of marketing pharmaceuticals and medical products today.

Who Should Attend

Professionals involved in:

- Regulatory Affairs
- Marketing
- Communications
- Compliance
- Medical Information and Affairs
- Legal
- Senior Management

Schedule At-A-Glance

PRIMER | FRIDAY, MARCH 5

10:00AM-3:00PM	**Drug and Medical Device Ad Promo Primer**

DAY ONE | MONDAY, MARCH 8

9:45-10:00AM	**Welcome and Opening Remarks**
10:00-11:15AM	**Session 1:** FDA Update - What's New and What's Worth Reiterating?
11:15-11:30AM	Break
11:30AM-12:30PM	**Session 2:** Virtual Marketing and Promotion - Lessons from COVID and Future Impact
12:30-1:30PM	Break
1:30-2:15PM	**Session 3:** Search Engine Marketing and Optimization: Keywords, Metadata, and Beyond
2:15-2:30PM	Break
2:30-3:30PM	**Session 4:** Using Influencers, Endorsers, and Testimonials in Your #Sponsored Campaigns
3:30-3:45PM	Break
3:45-4:15PM	**Building Acumen:** P-Value Power Learning
4:15-4:20PM	**Day One Wrap-Up**

DAY TWO | TUESDAY, MARCH 9

10:00-10:05AM	**Welcome to Day Two**
10:05-10:35AM	Recent and Relevant – Insights from the DIA Ad Promo Working Group
10:35-11:35AM	**Session 5:** Updates from OPDP's Research Team
11:35-11:45AM	Break
11:45AM-12:15PM	**Session 6:** Industry Perspective - Application of OPDP Research to Enhance Promotional Materials (Case Study)
12:15-1:15PM	Break
1:15-2:15PM	**Session 7:** The Future of Marketing and Communication The Future of Marketing: Key Trends You Need to Understand in 2021 (and beyond)
2:15-2:30PM	Break
2:30-3:30PM	**Session 8:** Ad Promo and Digital Health: Recent Advances
3:30-3:45PM	Break
3:45-4:45PM	**Session 9:** How to Apply the CFL Guidance: References and Disclaimers
4:45-4:50PM	**Day Two Wrap-Up**

DAY THREE | WEDNESDAY, MARCH 10

10:00-10:15AM	**Welcome to Day Three and Ad Promo Tribute**
10:15-11:30AM	**Session 10:** OPDP Core Launch Review -FDA and Industry Perspectives
11:30-11:45AM	Break
11:45AM-12:45PM	**Session 11:** Targeted Advertising and Patient Privacy: Use of Sensitive Information
12:45-1:45PM	Break
1:45-2:30PM	**Session 12:** Beyond the Letter-Recent and Relevant Legal Cases
2:30-2:45PM	Break
2:45-3:30PM	**Tips, Tools, and Templates:** Developing Brief Summaries, Major Statements and Important Safety Information
3:30-3:40PM	Break
3:40-4:10PM	**Open Q&A with Program Committee**
4:10-4:20PM	Break
4:20-4:50PM	**Meet and Greet with OPDP Staff**
4:50-5:05PM	**Closing Remarks**

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Learning Objectives

At the end of this conference participants should be able to:

- Discuss the latest FDA policies, guidance's and how they apply on a practical basis to day to day oversight of advertising and promotional materials for biopharmaceuticals and medical products
- Describe how other companies are interpreting policies and applying them to their current marketing strategies
- Evaluate risk and identify mitigation strategies associated with virtual medical promotion and online marketing tools
- Apply the latest policies to better communicate with all audiences, including payers
- Select and implement effective digital and social media strategies to meet the challenges of ensuring compliance with FDA regulatory requirements

Continuing Education Credit

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This session is designated for up to 18.25 contact hours or 1.825 continuing education units (CEU's). Type of Activity: Knowledge

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, APRIL 23, 2021

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. If ACPE credit is not requested by **Friday April 23, 2021**, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit www.cpemonitor.net.

DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET).

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer .5* CEUs for this conference. Participants must complete the entire conference in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

*IACET CEUs are only available for the Primer.

Continuing Legal Education

For attorneys who would like to receive continuing legal education credits for attending The 2021 Advertising and Promotion Regulatory Affairs Conference, please complete your state's application for credit and submit accordingly. If you require additional information, please contact **CE@DIAglobal.org**.

Credit Allocation

Drug and Medical Device Ad Promo Primer: 4.5 contact hours or .45 CEUs, Type of Activity: Knowledge, 0286-0000-21-034-L04-P; IACET: .5 CEUs

Conference Day 1: 4.5 contact hours or .45 CEUs, Type of Activity: Knowledge, 0286-0000-21-035-L04-P

Conference Day 2: 5 contact hours or .5 CEUs, Type of Activity: Knowledge, 0286-0000-21-036-L04-P

Conference Day 3: 4.25 contact hours or .425 CEUs, Type of Activity: Knowledge, 0286-0000-21-037-L04-P

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the live virtual conference, you must virtually attend the Primer and/or individual days of the conference, in their entirety, complete and return a CE Verification of Attendance Form (see instructions below), complete the post program evaluation and request CE credit online through My Transcript (see instructions below). Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, March 24, 2021**.

If you are claiming ACPE credit for this event you must

1. Attend the entire live Primer and/or individual days of the conference in their entirety
2. Complete a Verification of Attendance Form
3. Send back to **CE@DIAglobal.org** by **March 17, 2021**
4. Access your DIA account and select My Transcript to claim your ACPE credit, available on **Wednesday, March 24, 2021**

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- Select **My Transcripts** then **Manage My Transcripts**

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DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices. Disclosure statements are included with each speaker's biographical sketch.

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

To view DIA's Disclosure and Grievance Policies, visit **DIAglobal.org/CE**

PRIMER | FRIDAY, MARCH 5

10:00AM-3:00PM

Drug and Medical Device Ad Promo Primer

Instructors:

Dale Cooke, JD, MA, President, PhillyCooke Consulting

Kevin Madagan, JD, Partner, Reed Smith, LLP

Darshan Kulkarni, JD, PharmD, MS, Principal Attorney, The Kulkarni Law Firm

Julia Lake, JD, Associate, Reed Smith, LLP

DIA's extremely popular 2020 Ad Promo Primer returns again this year. Participants in the 2021 primer will be able to choose a drug/biologic or medical device track and may even switch between tracks throughout the day. This flexibility and expanded offering are designed to allow for more nuanced discussions about promotional standards, tactics, execution, and enforcement. The primer will be interesting, practical, and vital for those new to the field as well as experienced professionals who are seeking a refresher. The primer is designed for regulatory, legal, medical, compliance, or marketing professionals, their advisers, and consultants, or for anyone else in the field of prescription drugs and medical device product promotion. Instructors will provide clear and practical background and insights to field your most difficult questions.

Medical Device Promotion Track Highlights

This track will provide the professionals responsible for the advertising and promotion of medical devices with the background to get the most out of the main conference and know how to ensure that medical device communications comply with all relevant standards.

At the conclusion of this track, the participant should be able to:

- Describe the scope of the FDA's authority over medical device promotion
- Apply the relevant FDA standards to promotional messages about medical devices
- Identify when to look to other agencies (especially FTC) for promotional standards

Drug Promotion Track Highlights

This course is designed to provide background information for you to better understand the conference content. The leaders will provide an introductory foundation for anyone working in our current regulatory environment. Whether you are a regulatory, legal, medical, compliance, or marketing professional, the information will be interesting, practical, and vital.

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

- Discuss the current regulatory/compliance environment pertaining to the advertising and promotion of prescription drugs, vaccines, and biologics
- Describe FDA advertising and promotional requirements, including claim support requirements, fair balance expectations, internet and social media challenges, product booths at medical conventions, adherence and preference programs, patient involvement and outreach, disease state programs, and public relations challenges
- Assess the importance of the promotional review process, and be equipped to serve as a leading member of a promotional review committee

DAY ONE | MONDAY, MARCH 8

9:45-10:00AM

Welcome and Opening Remarks

Session Co-Chairs

Micheline Awad, MBA, Director Regulatory Affairs, Advertising and Promotion, Neurocrine Biosciences, Inc.

Kimberly Belsky, MS, Executive Director Regulatory Policy & Intelligence and Labeling Operations, Mallinckrodt Pharmaceuticals

10:00-11:15AM

Session 1: FDA Update - What's New and What's Worth Reiterating?

Session Co-Chairs
Wayne Pines, President, Health Care, APCO Worldwide Inc.

Catherine Gray, PharmD, Acting Director, Office of Prescription Drug Promotion, OMP, CDER, FDA

This session will feature senior representatives from CDER and CBER who will provide updates on recent FDA advertising and promotion activities, including compliance actions, process considerations, and goals for 2021.

OPDP Updates - Looking Back, Looking Forward
Catherine Gray, PharmD, Acting Director, Office of Prescription Drug Promotion, OMP, CDER, FDA

Response to OPDP Compliance Actions in eCTD
Jason Cober, Lead Project Manager, Office of Prescription Drug Promotion, CDER, FDA

Speakers
Lisa Stockbridge, PhD, Branch Chief, Advertising and Promotional Labeling Branch, OCBQ, CBER, FDA

Deborah Wolf, JD, Regulatory Counsel, Office of Product Evaluation and Quality, FDA

11:15-11:30AM

Break

11:30AM-12:30PM

Session 2: Virtual Marketing and Promotion - Lessons from COVID and Future Impact

Session Chair
Kimberly Belsky, MS, Executive Director Regulatory Policy & Intelligence and Labeling Operations, Mallinckrodt Pharmaceuticals

Over the past year, the COVID-19 pandemic has significantly limited industry access to healthcare providers and challenged traditional detailing and educational approaches. As a result, medical product promotion has

shifted to emphasize a range of virtual tactics and remote strategies, such as virtual conference booths, online speaker programs, e-detailing, video conferencing, webinars, social media, email and SMS campaigns, and more. In this session, panelists will explore the legal and regulatory risks and mitigation strategies that should be considered in virtual and remote promotional strategies, examine the lessons learned, and discuss the persistence and impact of virtual marketing and remote engagement post-pandemic.

Promotional Distancing: Exploring Risks in Virtual Strategies During a Pandemic and Beyond
Heather Banuelos, JD, Counsel, FDA and Life Sciences, King & Spalding

Virtual Conferences: Lessons From COVID and Future Impact
Olivia Walker, PharmD, Manager, Advertising & Promotion, Regulatory Affairs America, Bayer

12:30-1:30PM **Break**

1:30-2:15PM **Session 3:** Search Engine Marketing and Optimization: Keywords, Metadata, and Beyond

Session Chair
Dale Cooke, JD, MA, President, PhillyCooke Consulting

Online marketing is essential for pharmaceutical brands, and search engines are the key to online success. With ongoing FDA enforcement on search engine marketing, companies need to use the tools to reach online audiences compliantly. This session will give attendees the knowledge they need to review online materials with confidence.

Speaker
Dale Cooke, JD, MA, President, PhillyCooke Consulting

2:15-2:30PM **Break**

2:30-3:30PM **Session 4:** Using Influencers, Endorsers, and Testimonials in Your #Sponsored Campaigns

Session Chair
Joanne Hawana, JD, MS, Member, Mintz, Levin, Cohn, Ferris, Glovsky & Popeo P.C

Session Co-Chair
Heather Banuelos, JD, Counsel, FDA and Life Sciences, King & Spalding

In today's world of social media and the rise in influencer marketing throughout all industries, patient and physician endorsements for medical products can lend authenticity and emotional appeal to the biopharma marketing mix. To integrate testimonials, ambassadors, influencers, and spokespersons into their toolbox, marketers must understand the FDA and FTC laws, rules, and regulations applying to endorsements. This session will explore the legal and regulatory compliance issues that arise, as well as ways to safely, ethically, and transparently harness the great potential of patient and provider voices to full effect.

Speakers
Laura Sullivan, JD, Senior Attorney, Division of Advertising Practices, Federal Trade Commission

Nicole Hoadley, MBA, Vice President, Client Services, Snow Companies, LLC

Anna Williams, MS, Associate Director, Alkermes, Inc.

3:30-3:45PM **Break**

3:45-4:15PM **Building Acumen:** P-Value Power Learning

Session Chair
Kimberly Belsky, MS, Executive Director Regulatory Policy & Intelligence and Labeling Operations, Mallinckrodt Pharmaceuticals

This power session will build your acumen on understanding p-values and the role of confidence intervals (CIs) and minimum clinically important differences (MCIDs) in interpreting study results and statistical significance. Published scientific conclusions often apply the concept of statistical significance, commonly assessed with p-values. However, in light of common misconceptions concerning p-values, researchers may elect to supplement p-values with other approaches, such as CIs and MCIDs. Alternative approaches also become relevant in the context of large real-world evidence studies.

Speakers
Elaine Böing, MPH, BPharm, Director, Health Economics and Outcomes Research (HEOR), Rare Disease, US Medical Affairs, Ipsen Biopharmaceuticals, Inc.

4:15-4:20PM **Day One Wrap-Up**

DAY TWO | TUESDAY, MARCH 9

10:00-10:05AM **Welcome to Day Two**

10:05-10:35AM **Recent and Relevant** – Insights from the DIA Ad Promo Working Group

Session Chair
Kimberly Belsky, MS, Executive Director Regulatory Policy & Intelligence and Labeling Operations, Reg, Mallinckrodt Pharmaceuticals

Session Co-Chair
Renee Ambrosio, Department Head, Advertising & Promotion, Regulatory Affairs, Advertising & Promotion, Regulatory Affairs, Merck & Co., Inc.

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 will include: enforcement letter insights, biosimilar and generic promotion, recent legal cases, "who's doing what" EUA promotion sites, enforcement letter trends, the role of the MSL and HEOR, and ex-US regulations/guidance (UK, Australia). You will also learn how you can build your acumen throughout the year by becoming involved in the Working Group.

10:35-11:35AM **Session 5:** Updates from OPDP's Research Team

Session Chair
Lucy Rose, MBA, President, Lucy Rose and Associates, LLC.

Individual FDA/OPDP researchers will present findings from OPDP research studies. Attendees will gain a better understanding of the FDA/OPDP Research program and how it may contribute to knowledge, guidance, and policy development. This session is designed to educate attendees on the regulatory research work FDA has done to help inform policy and guidance development.

Experimental Study of Risk Information Amount and Location in Direct-to-Consumer Print Ads
Kathryn Aikin, PhD, MS, Senior Social Science Analyst, Research Team Lead, OPDP, CDER, FDA

Visual Images of Prescription Drug Benefits in Direct-to-Consumer Television Advertisements
Helen Sullivan, PhD, MPH, Social Science Analyst, OPDP, CDER, FDA

What Influences Healthcare Providers' Prescribing Decisions? Results from a National Survey
Amie O'Donoghue, PhD, Social Science Analyst, OPDP, CDER, FDA

Utilization of Adequate Provision in Prescription Drug Broadcast Ads Among Low- and Non-Internet Users
Kevin Betts, PhD, Social Science Analyst, OPDP, CDER, FDA

11:35-11:45AM **Break**

11:45AM-12:15PM **Session 6:** Industry Perspective - Application of OPDP Research to Enhance Promotional Materials (Case Study)

Session Chair
Kimberly Belsky, MS, Executive Director Regulatory Policy & Intelligence and Labeling Operations, Mallinckrodt Pharmaceuticals

The Office of Prescription Drug Promotion (OPDP) has an active research program designed to investigate applied and theoretical issues of relevance to direct-to-consumer (DTC) and professional promotional prescription drug materials. Using case studies, this session will provide valuable insights to show how OPDP research outcomes can augment the development of promotional materials to enhance clarity and comprehension by consumers and healthcare professionals.

Speakers
Kimberly Belsky, MS, Executive Director Regulatory Policy & Intelligence and Labeling Operations, Mallinckrodt Pharmaceuticals

Kevin Madagan, JD, Partner, Reed Smith, LLP

12:15-1:15PM	**Break**
1:15-2:15PM	**Session 7:** The Future of Marketing and Communication The Future of Marketing: Key Trends You Need to Understand in 2021 (and beyond) **Session Chair** **Dale Cooke, JD, MA**, President, PhillyCooke Consulting **Session Co-Chair** **Mark Bard, MBA, MHA**, Founder, Digital Health Coalition Marketing and customer engagement strategies experienced a major disruption in 2020. Brands and organizations were forced to launch, replace, or quickly evolve their strategies over the past year to keep pace with the combination of technology, market, and economic forces in play. What's ahead for health and pharma marketing? What marketing trends matter? Which trends are hype? What emerging trends will change marketing the most in five years? **Speakers** **R.J. Lewis, MBA**, Founder, President & CEO, eHealthcare Solutions **David Bernstein**, Chief Revenue Officer, Everyday Health Group Consumer **Panelist** **Melinda Decker, MBA, MS**, Chief Commercial Officer, Mymee
2:15-2:30PM	**Break**
2:30-3:30PM	**Session 8:** Ad Promo and Digital Health: Recent Advances **Session Chair** **Mary Raber Johnson, PhD, RAC**, Assistant Professor, Clinical, The Ohio State, University, College of Pharmacy Digital health is expanding how we think about healthcare through strategic use of evolving technology and application of digital health, including the recent launch of the US FDA's Digital Health Center of Excellence (DHCoE). The following session will review these topics and discuss the speakers' perspectives on the future of digital health, including an interactive question/answer session. **Speakers** **Bakul Patel, MBA, MS**, Director, Digital Health Center of Excellence (DHCoE), CDRH, FDA **Ritesh Patel**, Chief Digital Officer, Health, Ogilvy Consulting
3:30-3:45PM	**Break**
3:45-4:45PM	**Session 9:** How to Apply the CFL Guidance: References and Disclaimers **Session Chair** **Micheline Awad, MBA**, Director Regulatory Affairs, Advertising and Promotion, Neurocrine Biosciences, Inc. This session will focus on applying the CFL guidance to various data presentations in promotional materials. You will learn how to effectively collaborate with various colleagues across your organization to properly disclose and support CFL content for various types of analyses/data such as sub-group analyses, post-hoc analyses, and long-term follow up trials (pivotal or other). Using examples, the panel will provide an interactive learning experience to help drive the conversation and help you to determine the appropriate level of evidentiary support and disclaimers needed to support claims, in accordance with the CFL guidance. **Speakers** **Glenn Byrd, MBA**, President, GByrd Ad-Promo Solutions, LLC **Linda Kollmar, MD**, Executive Director, Team Lead Medical Consult and Review Physicians, Merck & Co., Inc.
4:45-4:50PM	**Day Two Wrap-Up**

DAY THREE | WEDNESDAY, MARCH 10

10:00-10:15AM

Welcome to Day Three and Ad Promo Tribute

Session Chair
Wayne Pines, President, Health Care, APCO Worldwide Inc.

10:15-11:30AM

Session 10: OPDP Core Launch Review -FDA and Industry Perspectives

Session Co-Chairs
Sheetal Patel, PharmD, Head, Regulatory Advertising and Promotion, Johnson & Johnson International

Virginia Foley, Principal Consultant, Opus Regulatory Inc.

Come join FDA-OPDP staff along with industry experts, each with unique perspectives, as they discuss best practices and strategies of a Request for Advisory Comments submission and how they apply to Direct-to-Consumer (DTC) broadcast advertisements, new product launches and accelerated approvals (subpart E/H), and press releases. We will also discuss the various pathways for submitting a Request for Advisory Comment, both in eCTD and non-eCTD format, as well as delving into some recommendations to help Sponsors construct Advisory submissions.

Speakers
Jason Cober, Lead Project Manager, Office of Prescription Drug Promotion, CDER, FDA

Rachel Conklin, MS, Regulatory Review Officer, FDA

11:30-11:45AM

Break

11:45AM-12:45PM

Session 11: Targeted Advertising and Patient Privacy: Use of Sensitive Information

Session Chair
Kevin Madagan, JD, Partner, Reed Smith, LLP

This session will review the key patient privacy protections in the United States and the restrictions they pose on the use of patient data in marketing campaigns. The session will also explore the nuances of how the National Advertising Initiative's Code of Conduct, "Health Audience Segments" guidelines, could influence your ability to engage in targeted advertising using sensitive patient information.

Speakers
Anthony Matyjaszewski, JD, Vice President for Compliance & Member Development, Network Advertising Initiative

Stefani Klaskow, Industry Lead, Google

12:45-1:45PM

Break

1:45-2:30PM

Session 12: Beyond the Letter-Recent and Relevant Legal Cases

Session Chair
Carla Brooks, MSc, RAC, Senior Director, Regulatory Affairs, Advertising & Promotion, Blueprint Medicines Corporation

There have been some interesting legal cases in the past year or so that are relevant to what we do—e.g., recent Park Doctrine, Lanham Act, and False Claims cases. Topics to include: Intended use proposed regulation, the recent Purdue, McKinsey, and Humira Settlements, and OIG Special Fraud Alert.

Speakers
Trish Dring, JD, Vice President, Associate General Counsel, Aurinia Pharmaceuticals Inc.

Katherine Norris, MPA, Director, Life Sciences - Governance, Risk Management and Compliance, Guidehouse

2:30-2:45PM

Break

2:45-3:30PM

Tips, Tools, and Templates: Developing Brief Summaries, Major Statements and Important Safety Information

Session Co-Chairs
Mark Gaydos, Vice President, US Advertising & Promotion, Region North America, Global Regulatory Affairs, Sanofi

Victoria Tamarkin, MS, Founding Partner & Principal Consultant, Global Regulatory Affairs, Promotional Compliance, Tamarkin Consulting, LLC.

This session will provide practical suggestions for the development and implementation of documents that are critical to the adequate and timely communication of product risk information. Presenters will cover brief summaries used in print advertising, consumer brief summaries used in DTC advertising and promotional labeling, major statements included in DTC TV ads and both consumer and professional important safety information (ISI) integrated within promotional labeling.

Speaker
Kevin Gomba, Associate Director, Global Regulatory Affairs, Promotion Compliance, Development & Commercialization, Otsuka America Pharmaceutical Co Inc.

3:30-3:40PM — **Break**

3:40-4:10PM — **Open Q&A with Program Committee**

4:10-4:20PM — **Break**

4:20-4:50PM — **Meet and Greet with OPDP Staff**

Session Co-Chairs
Catherine Gray, PharmD, Acting Director, Office of Prescription Drug Promotion, OMP, CDER, FDA

Micheline Awad, MBA, Director Regulatory Affairs, Advertising and Promotion, Neurocrine Biosciences, Inc.

Kimberly Belsky, MS, Executive Director Regulatory Policy & Intelligence and Labeling Operations, Mallinckrodt Pharmaceuticals

This session will feature eighteen OPDP staff members participating in a meet and greet opportunity with conference attendees. Reviewers or Team Leaders from the Metabolic & Endocrine, Anti-Infective, Cardiovascular, Medical Imaging, Ophthalmology, Renal, Transplant, Addiction, Analgesics, Anesthetics, Antivirals, Dental, Dermatology, Osteoporosis, Reproductive, Urology, Neurology/Psychiatry, and Oncology dockets will engage in an informal conversation about their experience in OPDP. OPDP's Deputy Directors for the Division of Advertising and Promotion Review 1 and 2, the Acting OPDP Director and the Assistant to the Director will also engage in the conversation.

Panelists
Joanne Hawana, JD, MS, Member, Mintz, Levin, Cohn, Ferris, Glovsky & Popeo P.C.

Twyla Thompson, PharmD, Deputy Division Director, Division of Advertising and Promotion 2, OPDP, FDA

Meena Savani, **PharmD**, Regulatory Review Officer, Division of Advertising and Promotion 2, FDA

Charuni Shah, PharmD, Regulatory Review Officer, Division of Advertising and Promotion 2, OPDP, CDER, FDA

James Dvorsky, PharmD, Team Leader, Division of Advertising and Promotion 2, FDA

Samuel Skariah, PharmD, Team Leader, Division of Advertising and Promotion 1, CDER/DDMAC, FDA

Lisa Hubbard, PharmD, RPh, Deputy Division Director, Division of Advertising and Promotion 1, OPDP, FDA

Matthew Falter, PharmD, RPh, Team Leader, Division of Advertising and Promotion 2, CDER, FDA

Dhara Shah, PharmD, Regulatory Review Officer, Division of Advertising and Promotion 1, FDA

Sapna Shah, PharmD, Regulatory Review Officer, Division of Advertising and Promotion 1, OPDP, CDER, FDA

Christine Bradshaw, PharmD, RAC, Regulatory Review Officer, Division of Advertising and Promotion 1, OPDP, CDER, FDA

Jean-Ah Kang, PharmD, Special Assistant to the Director, Office of Prescription Drug Promotion, CDER, FDA

Lynn Panholzer, PharmD, Regulatory Review Officer, Division of Advertising and Promotion 1, OPDP, CDER, FDA

Nazia Fatima, PharmD, MBA, Regulatory Review Officer, Division of Advertising and Promotion 1, FDA

Trung-hieu (Brian)Tran, PharmD, MBA, Team Leader, Division of Advertising and Promotion 1, OPDP, CDER, FDA

Nima Ossareh, PharmD, RAC, Regulatory Review Officer, Division of Advertising and Promotion 1, FDA

Susannah O'Donnell, MPh, RAC, Team Leader, Division of Advertising and Promotion 1, FDA

Catherine Gray, PharmD, Acting Director, Office of Prescription Drug Promotion, OMP, CDER, FDA

4:50-5:05PM — **Closing Remarks**