DIA

Advertising and Promotion Regulatory Affairs Conference

Primer: March 4 Virtual | Conference: March 8-9 Virtual

PROGRAM CO-CHAIRS

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Lucy Rose, MBA
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Overview

DIA's *Advertising and Promotion Regulatory Affairs Conference* explores the current state of compliance for marketing both biopharmaceuticals and medical devices. 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.

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 medical products. You 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 devices today.

Who Should Attend

Professionals involved in:

- Regulatory Affairs
- Marketing
- Communications
- Compliance
- Medical Information and Affairs
- Legal
- Patient Engagement

Schedule At-A-Glance

PRE-EVENT PROMOTIONAL WEBINAR | WEDNESDAY, FEBRUARY 2

Sessions are held in ET

12:00-1:00PM	**Avoid Unwanted Attention to Your Press Releases**

PRIMER | FRIDAY, MARCH 4

10:00AM-3:00PM	Drug and Biologic Ad Promo Primer

DAY ONE | TUESDAY, MARCH 8

8:00-9:30AM	**Welcome, Opening Remarks and Session 1:** FDA Updates
9:30-9:40AM	Session Transition
9:40-10:40AM	**Session 2:** From Unbranded to Branded: The Role and Risks of Disease Awareness
10:40-11:15AM	Break, Visit the Virtual Exhibit Hall
11:15-11:45AM	**Power Learning:** DTCTV vs Online Video Ads
11:45-11:55AM	Session Transition
11:55AM- 12:55PM	**Session 3:** Pro Tip! Effective Engagement between FDA's OPDP/APLB/CVM and Industry Leaders
12:55-2:00PM	Break, Visit the Virtual Exhibit Hall
2:00-2:45PM	**Power Learning:** PRC Best Practices
2:45-3:15PM	Break, Visit the Virtual Exhibit Hall
3:15-4:30PM	**Session 4:** Drug/Device Company Interactions with Patient Advocacy Groups: Working Collaboratively and Compliantly
4:30-4:40PM	Session Transition
4:40-5:10PM	**Open Discussion**

DAY TWO | WEDNESDAY, MARCH 9

8:00-8:35AM	**Welcome and Opening Remarks and Recent and Relevant** – Insights from the DIA Ad Promo Working Group
8:35-8:45AM	Session Transition
8:45-9:45AM	**Session 5:** OPDP Research Update
9:45-10:15AM	Break, Visit the Virtual Exhibit Hall
10:15-11:15AM	**Session 6:** Global AdPromo - Scenarios and Insights on Prescription Medicines and Medical Devices
11:15-11:25AM	Session Transition
11:25AM-12:25PM	**Session 7:** Intersection of Labeling and AdPromo - OPDP and Industry Perspectives
12:25-1:30PM	Break, Visit the Virtual Exhibit Hall
1:30-2:30PM	**Session 8:** OPDP Meet and Greet
2:30-3:00PM	Refreshments, Exhibits, and Networking Break
3:00-4:00PM	**Session 9:** Career Forum and Closing Remarks

Learning Objectives

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

- Discuss current regulatory/legal/compliance environment pertaining to the advertising and promotion of prescription drugs, vaccines, and biologics
- 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
- Apply lessons from recent compliance actions to current advertising and promotion review work
- Recognize material differences for disease awareness in unbranded and branded communications
- Describe the regulatory framework for evaluating traditional and online DTC TV ads
- Describe the role and objectives of the FDA on advertising and promotion issues
- Apply key learnings and best practices shared by the panelists with their own Promotional Review Committee reviews
- Develop an understanding of the benefits and value of involving patients and caregivers in the drug and medical device development process
- Compare AdPromo differences in specific country regulations and requirements
- Discuss the various professional growth and career opportunities available in the advertising and promotion regulatory space

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 **13.75** contact hours or **1.375** continuing education units (CEU's). Type of Activity: Knowledge

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, APRIL 22, 2022

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 22, 2022**, 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.

Drug Information Association (DIA) is accredited by the International Association for Continuing Education and Training (IACET) and is authorized to issue the IACET CEU.

As an IACET Accredited 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 2022 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

March 4, 2022 - Drug and Biologic Ad Promo Primer: 4.5 contact hours or .45 CEUs, Type of Activity: Knowledge, UAN: 0286-0000-22-007-L04-P Knowledge; IACET:.5 CEUs
March 8, 2022 - Conference Day 1: 6 contact hours or .6 CEUs, Type of Activity: Knowledge, UAN: 0286-0000-22-008-L04-P
March 9, 2022 - Conference Day 2: 3.25 contact hours or .325 CEUs, Type of Activity: Knowledge, UAN: 0286-0000-22-009-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 23, 2022.**

If you are claiming ACPE credit for this event you must

1. Attend the entire live virtual 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 16, 2022**
4. Access your DIA account and select My Transcript to claim your ACPE credit, available on **Wednesday, March 23, 2022**

TO ACCESS MY TRANSCRIPT

- Visit DIAglobal.org
- **Sign In** with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Select **My Transcripts** then **Manage My Transcripts**

ACCESS PRESENTATIONS

- Visit DIAglobal.org
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- Select **My Account** from the menu
- Choose **My Presentation**

Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder. **Presentations will be available for six months post conference.*

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**

PRE-EVENT PROMOTIONAL WEBINAR | WEDNESDAY, FEBRUARY 2

Sessions are held in ET

12:00-1:00PM

Avoid Unwanted Attention to Your Press Releases

Session Co-Chairs
Dale Cooke, JD, MS, President, PhillyCooke Consulting

Robert Dean, Director, Advertising and Promotion, Merck

This pre-event promotional webinar will address some of the issues companies are facing when developing press releases and why these communications can be challenging. The webinar will cover the historical regulation of Press Releases by the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC)/Office of Prescription Drug Promotion (OPDP), draw key concepts from previous FDA enforcement and illustrate principles to avoid FDA action. The webinar will also frame the key legal and regulatory considerations companies should be aware of when issuing Press Releases.

At the conclusion of this webinar, participants should be able to

- Understand the historical regulation of Press Releases
- Understand the regulatory/legal framework for evaluating Press Releases
- Apply learnings in the creation of compliant Press Releases

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

Robert Dean, Director, Advertising and Promotion, Merck

PRIMER | FRIDAY, MARCH 4

10:00AM-3:00PM

Drug and Biologic Ad Promo Primer

Session Chair
Micheline Awad, MBA, Senior Director, Regulatory Affairs – Advertising, Promotions, and Labeling, Turning Point Therapeutics, Inc.

DIA's Ad Promo Primer returns this year for participants to learn about prescription drug and biologic promotional standards, tactics, execution, and enforcement. The primer is practical and key for those new to the field as well as experienced professionals who are seeking a refresher. The primer will be virtual and is designed for Regulatory, Legal, Medical, Compliance, or Marketing professionals, their advisers, and consultants, or for Students or anyone else in the field interested in networking while learning more about prescription drug or biologic product promotion.

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

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

Dale Cooke, JD, MA, President, PhillyCooke Consulting

Micheline Awad, MBA, Senior Director, Regulatory Affairs – Advertising, Promotions, and Labeling, Turning Point Therapeutics, Inc.

Kim Belsky, MS, Executive Director, Regulatory Policy & Intelligence and AdPromo Regulatory Affairs, Mallinckrodt Pharmaceuticals

DAY ONE | TUESDAY, MARCH 8

8:00-9:30AM **Welcome, Opening Remarks and Session 1:** FDA Updates

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

This session will feature senior representatives from FDA's Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH) and Center for Veterinary Medicine (CVM). The representatives will provide updates on recent FDA advertising and promotion activities, including compliance actions, process modifications, program areas and goals for 2022.

Speakers
OPDP Updates – It's More Than Compliance
Catherine Gray, PharmD, Director, Office of Prescription Drug Promotion, OMP, CDER, FDA

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

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

Kathryn Dennehy, DVM, Veterinary Medical Officer, FDA | CVM | Office of Surveillance and Compliance | Division of Surveillance

9:30-9:40AM **Session Transition**

9:40AM-10:40PM **Session 2:** From Unbranded to Branded: The Role and Risks of Disease Awareness

Session Chairs
Virginia Foley, Head of Marketing and Strategic Business Development, Opus Regulatory Inc.

Historically regarded as non-promotional communications, disease awareness and help-seeking communications have surged and evolved over time. This session will explore what it means to actively promote and advertise a disease or condition – as opposed to a product – in the current legal and regulatory landscape. Approaches and best practices pre- and post- product approval may vary, including when disease awareness is conducted, the scope and extent of disease state or treatment information (e.g., product classes, treatment options), who shares it (e.g., Marketing, Medical, or Sales functions), to whom it is shared (consumers vs. healthcare providers), and why. Panelists will discuss whether the traditional considerations and hallmarks of disease awareness communications still apply in light of newer digital technologies and FDA's First Amendment policy. Finally, this session will highlight related advertising activities – neither branded nor disease state education – in the form of unbranded ads such as digital banners and sponsored links.

Speakers
Dara Katcher Levy, JD, Director, Hyman Phelps & McNamara P.C.

Michael Sauers, RAC, Director, Global Regulatory Affairs - Advertising and Promotion, Eli Lilly and Company

Virginia Foley, Head of Marketing and Strategic Business Development, Opus Regulatory Inc

10:40-11:15AM **Break, Visit the Virtual Exhibit Hall**

11:15-11:45AM **Power Learning:** DTCTV vs Online Video Ads

Session Co-Chairs
Robert Dean, MBA, Director, Advertising and Promotion, Merck

Mark Gaydos, Vice President & Global Head, Advertising, Promotion & Labeling, Sanofi

This session will explore direct-to-consumer (DTC) television ads and the increasingly more common appearance of drug promotion via online DTC videos. Panelists and participants will examine the important distinction between advertising and promotional labeling in this context as well as the challenges associated with applying the appropriate standard to online prescription drug videos appearing on platforms in markedly different contexts (e.g., videos posted on sponsor websites, video sharing sites, and online streaming services). Finally, the panelists will address commonly raised questions on this topic.

Speaker
Robert Dean, MBA, Director, Advertising and Promotion, Merck

Mark Gaydos, Vice President & Global Head, Advertising, Promotion & Labeling, Sanofi

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11:45-11:55AM **Session Transition**

11:55AM- 12:55PM **Session 3:** Pro Tip! Effective Engagement between FDA's OPDP/APLB/CVM and Industry Leaders

Session Co-Chairs
Fadwa Almanakly, PharmD, Vice President & Head, Advertising and Promotion, Regulatory Affairs Americas, Bayer Pharmaceuticals

Sheetal Patel, PharmD, Head, Compliance and Regulatory Advertising and Promotion, Johnson & Johnson International

For US regulatory affairs professionals, understanding of the role and objectives of the FDA on advertising and promotion issues is the foundation for establishing an effective, productive relationship with FDA. During this session, you will gain insights from both FDA and regulatory industry representatives to identify approaches to effectively interact with the FDA and begin to build and sustain a strategic, successful working relationship with FDA.

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

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

Kathryn Dennehy, DVM, Veterinary Medical Officer, FDA | CVM | Office of Surveillance and Compliance | Division of Surveillance

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

Fadwa Almanakly, PharmD, Vice President & Head, Advertising and Promotion, Regulatory Affairs Americas, Bayer Pharmaceuticals

Sheetal Patel, PharmD, Head, Compliance and Regulatory Advertising and Promotion, Johnson & Johnson International

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12:55-2:00PM **Break, Visit the Virtual Exhibit Hall**

2:00-2:45PM **Power Learning:** PRC Best Practices

Session Chair
Georgina Lee, PharmD, Senior Director, Regulatory Affairs Advertising & Promotion and Labeling, Sage Therapeutics

This session will feature a moderated panel with experts from Regulatory Affairs, Medical Affairs, Legal & Compliance to discuss best practices and successful ways of working together in Promotional Review Committees (PRC). The panelists will share their views on topics of interest such as relationship building, time management, key learnings from material review and ways to stay on top of advancing technology and social media.

Moderator
Georgina Lee, PharmD, Senior Director, Regulatory Affairs Advertising & Promotion and Labeling, Sage Therapeutics

Panelists
Janet Gottlieb, PhD, Executive Director, Medical Compliance Excellence, Material Review, AbbVie

Elizabeth Kim, JD, Deputy General Counsel, Mitsubishi Tanabe Pharma – North America

Richard Lem, PharmD, Senior Director, Regulatory Affairs Advertising and Promotion, TG Therapeutics, Inc.

2:45-3:15PM — **Break, Visit the Virtual Exhibit Hall**

3:15-4:30PM — **Session 4:** Drug/Device Company Interactions with Patient Advocacy Groups: Working Collaboratively and Compliantly

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

Over the past decade, the shift to patient-focused drug development, as well as the increasing reliance on real-world evidence to support regulatory applications for both drugs and devices, has elevated the importance of ensuring that Sponsors have strong relationships with patients and their advocates, ranging from caregivers to formal advocacy and educational groups. However, those relationships are often fraught with regulatory and compliance risks if communications between sponsors and patients/advocates about investigational products become promotional in nature, items of significant value are involved in the interaction, or protected health information is being collected, among other considerations. This session will allow for a candid discussion of potential pitfalls in the continuously evolving communications between Sponsors and patient groups, and share tips for how to avoid them in both the pre-and post-market settings.

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

Panelists
Derek Naten, Vice President, Government Affairs & Patient Advocacy, Mallinckrodt Pharmaceuticals

Dara Katcher Levy, JD, Director, Hyman, Phelps & McNamara, P.C.

Annie Kennedy, Chief of Policy & Advocacy, EveryLife Foundation for Rare Diseases

4:30-4:40PM — **Session Transition**

4:40-5:10PM — **Open Discussion**

Session Chair
Mark Gaydos, Vice President & Global Head, Advertising, Promotion & Labeling, Sanofi

Didn't get to ask a question in a session today? Join the Advertising and Promotion Regulatory Affairs Conference Committee to ask questions and discuss the days learnings.

8:00-8:30AM

Welcome and Opening Remarks and Recent and Relevant – Insights from the DIA Ad Promo Working Group

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

Kim Belsky, MS, Executive Director, Regulatory Policy & Intelligence and AdPromo Regulatory Affairs, Mallinckrodt Pharmaceuticals

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 Podcasts, digital/social media platforms, "Drug-Facts-Like" Brief Summary, enforcement letter insights, PhRMA code update, OPDP Research, 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.

Speakers
Renee Ambrosio, Department Head, Advertising & Promotion, Regulatory Affairs, Merck & Co., Inc.

Kim Belsky, MS, Executive Director, Regulatory Policy & Intelligence and AdPromo Regulatory Affairs, Mallinckrodt Pharmaceuticals

8:35-8:45AM

Session Transition

8:45-9:45AM

Session 5: OPDP Research Update

Session Co-Chairs
Kathryn Aikin, PhD, MS, Senior Social Science Analyst, Research Team Lead, OPDP, CDER, FDA

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

Individual FDA/OPDP researchers will present findings from OPDP research studies. Attendees will get an overview of the FDA/OPDP Research program and how it may contribute to knowledge, guidance, and policy development in the prescription drug advertising and promotion space.

Pre-recorded session, no live Q&A

Research Status Update
Kathryn Aikin, PhD, MD, Senior Social Science Analyst, Research Team Lead, OPDP, CDER FDA

Character-Space-Limited Online Prescription Drug Communications: Four Experimental Studies
Helen Sullivan, PhD, MPH, Social Science Analyst, OPDP, CDER FDA

Disease Awareness and Prescription Drug Communications on Television: Evidence for Conflation and Misleading Product Impressions
Kevin Betts, PhD, Social Science Analyst, FDA

How Physicians View Data of Uncertain Clinical Utility in Oncology Prescription Drug Promotion
Amie O'Donoghue, **PhD**, Social Science Analyst, OPDP, CDER, FDA

9:45-10:15AM

Break, Visit the Virtual Exhibit Hall

10:15-11:15AM

Session 6: Global AdPromo - Scenarios and Insights on Prescription Medicines and Medical Devices

Session Chair
Kim Belsky, MS, Executive Director, Regulatory Policy & Intelligence and AdPromo Regulatory Affairs, Mallinckrodt Pharmaceuticals

This panel of experts will address strategic and tactical considerations in a variety of global promotion scenarios for prescription medicines and medical devices (e.g., press release, social media, different

indications and uses, medical congresses, disease awareness, other learning opportunities). The session will provide insights and guardrails for various countries including Europe, UK, and Canada.

Panelists

Michael Blasi, MS, RPh, Executive Director, Scientific Communications and Operations, Mallinckrodt Pharmaceuticals

Erik Vollebregt, LLM, Partner, AXON Lawyers, Netherlands

John Wong, MPharm, Director, Scientific Affairs and Medical Information, TPIreg/ Innomar Strategies, an AmerisourceBergen Company, Canada

Karen Timmins, Senior Director, Head of Regulatory Advertising & Promotion, Global Regulatory Affairs, Takeda, Switzerland

11:15-11:25AM **Session Transition**

11:25AM-12:25PM **Session 7:** Intersection of Labeling and AdPromo - OPDP and Industry Perspectives

Session Co-Chairs

Kathleen Klemm, PharmD, MS, RAC, Deputy Director, FDA | CDER | OMP | Office of Prescription Drug Promotion | Division of Advertisi

Georgina Lee, PharmD, Senior Director, Regulatory Affairs Advertising & Promotion and Labeling, Sage Therapeutics

Product labeling negotiations between sponsors and FDA can shape the final language in the approved label that will be used as the basis for promotion. This session will explore the general process for labeling negotiations and how advertising and promotion expertise can be applied from the industry perspective and the role of OPDP during labeling review from the FDA perspective.

Speakers

Georgina Lee, PharmD, Senior Director, Regulatory Affairs Advertising & Promotion and Labeling, Sage Therapeutics

Kathleen Klemm, PharmD, MS, RAC, Deputy Director, FDA | CDER | OMP | Office of Prescription Drug Promotion | Division of Advertising

12:25-1:30PM **Break, Visit the Virtual Exhibit Hall**

1:30-2:30PM **Session 8:** OPDP Meet and Greet

Session Co-Chairs

Fadwa Almanakly, PharmD, Vice President & Head, Advertising and Promotion, Regulatory Affairs Americas, Bayer Pharmaceuticals

Micheline Awad, MBA, Senior Director, Regulatory Affairs – Advertising, Promotions, and Labeling, Turning Point Therapeutics, Inc.

This session will feature FDA staff members from the Office of Prescription Drug Promotion (OPDP), the Advertising and Promotional Labeling Branch (APLB), and the Regulatory Policy & Guidance Staff in the Office of Product Evaluation and Quality participating in a meet and greet opportunity with conference attendees. Staff members include reviewers, members of leadership, policy analysts and regulatory counsel.

Matthew Falter, PharmD, RPh, Deputy Division Director, DAPR2/OPDP, FDA

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

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

Nazia Fatima, MBA, PharmD, Consumer Safety Officer, Division of Advertising and Promotion 1, FDA

Kathleen David, BSN, Supervisory Consumer Safety Officer, Immediate Office, OPDP, FDA

Amy Muhlberg, PhD, Policy Analyst, Immediate Office, OPDP, FDA

Jennifer Chen, PharmD, MBA, RPh, Regulatory Review Officer, Division of Advertising and Promotion 1, FDA

Deborah Wolf, JD, Regulatory Counsel, FDA | CDRH | Office of Product Evaluation and Quality | Regulatory Policy & Guidance

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

Oluchi Elekwachi, PharmD, Safety Evaluator, FDA

2:30-3:00PM **Break, Visit the Virtual Exhibit Hall**

3:00-4:00PM **Session 9:** Career Forum and Closing Remarks

Session Chair
Micheline Awad, MBA, Senior Director, Regulatory Affairs – Advertising, Promotions, and Labeling, Turning Point Therapeutics, Inc.

Virginia Foley, Head of Marketing and Strategic Business Development, Opus Regulatory Inc.

Come join us as we share our experiences and ideas for career development. Topics will include:

- Interviewing
- Managing your career
- Mentor/Mentee
- How to transition between roles (e.g., stretch projects, development goals, diversifying skills)
- Fellowship programs
- Networking & relationship building (e.g., connecting to DIA communities, with other functions within your company)

Speakers
Micheline Awad, MBA, Senior Director, Regulatory Affairs – Advertising, Promotions, and Labeling, Turning Point Therapeutics, Inc.

Virginia Foley, Head of Marketing and Strategic Business Development, Opus Regulatory Inc.

Michael Sauers, RAC, Director, Global Regulatory Affairs - Advertising and Promotion, Eli Lilly and Company

Lisa Kelsey, Head of Commercial Labeling, Associate Group Director, Genentech, A Member of the Roche Group