

20th Annual Pharmaceutical and Medical Device Compliance Congress

MANDARIN ORIENTAL • WASHINGTON, DC
NOVEMBER 6 – 8, 2019

SPONSORED BY



THE
PHARMACEUTICAL
COMPLIANCE
FORUM

Follow Pharma Congress on:



Welcome

Jeff Kawalek

PCF Chair

Deputy Chief Compliance Officer

Jazz Pharmaceuticals

PCF Co-Chairs

Sujata Dayal, JD
Vice President,
Healthcare Compliance
& Privacy
Johnson & Johnson

Jennifer McGee, JD
Vice President, Chief
Compliance Officer,
Otsuka

Margaret Sparks, JD
Associate Vice President,
Ethics and Business
Integrity,
Sanofi

Donna White, CCEP
Vice President Contracts
and Compliance
Chiesi

Joe Zimmerman
Vice President, Chief
Compliance Officer
Ferring Pharmaceuticals

Deb Scanlon
PCF Administrator



The Pharmaceutical Compliance Forum



The Pharmaceutical Compliance Forum is a not-for-profit trade association of compliance professionals and legal counsel from over 75+ distinguished research-based pharmaceutical manufacturers and biotech companies.

Our members meet several times a year in an informal and open setting to discuss:

- *Current developments in the regulatory environment*
- *Best practice sharing*
- *Education*
- *Industry guidance and current events*

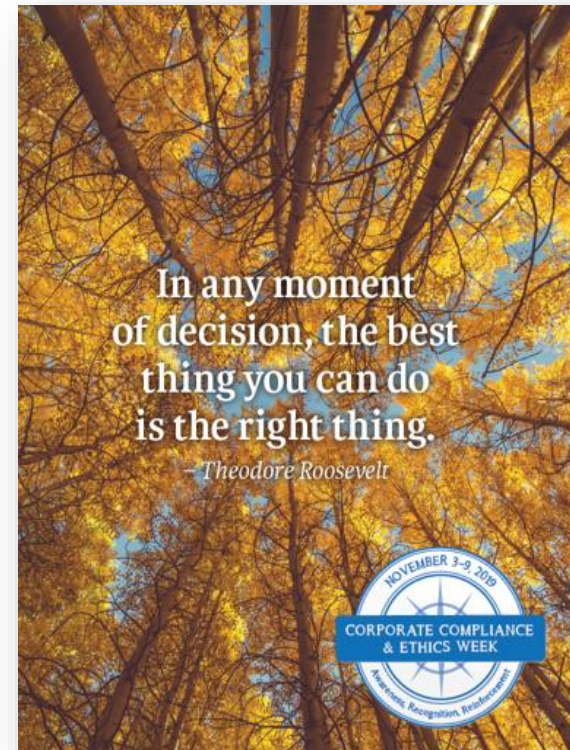
For more information on the benefits of becoming a member:

<http://www.pharmacomplianceforum.org/>

<http://www.pharmacomplianceforum.org/>

Corporate Compliance Week

November 3-9, 2019



We continue to GROW!

2000

*The First Annual
Pharmaceutical Industry
Regulatory &
Compliance*

67 Industry Attendees

Wednesday October 18, 2000
Grand Hyatt Hotel, Washington, DC

Co-Sponsored by:
Health Care Compliance Association
HCCA
In association with the
Food and Drug Law Institute
FDLI

Participating
Pharmaceutical
Companies Include:

Aventis
Eli Lilly
Merck
Pharmacia
SmithKline Beecham
Warner-Lambert

and Medical Education Collaborative
A Nonprofit Education Organization

2018

**Nineteenth Annual
Pharmaceutical
and Medical Device
Compliance Congress**

MANDARIN ORIENTAL · WASHINGTON, DC
NOVEMBER 7 - 9, 2018

245 Industry Attendees

A HYBRID CONFERENCE AND INTERNET EVENT

www.PharmaCongress.com

For Early Bird Registration, Register by Friday, September 21!

GOLD GRANTOR: **Deloitte.**

SILVER GRANTORS: **Grant Thornton**, **EY**, **Polaris**, **pwc**

BRONZE GRANTORS: **Arnold & Porter**, **BRG**, **Cooley**, **Cutting Edge**, **Dovetail**, **Covington**, **Deva Wright**, **NAVIGANT**, **HELIO**, **DEVA WRIGHT**, **NAVIGANT**, **KING & SPALDING**, **POZNANSKI**, **POTOMAC**, **HOPES & GRAY**, **SAI GLOBAL**, **SIDLEY**, **Skadden**

2019

**Twentieth Annual
Pharmaceutical
and Medical Device
Compliance Congress**

MANDARIN ORIENTAL · WASHINGTON, DC
NOVEMBER 6 - 8, 2019

293 Industry Attendees

A HYBRID CONFERENCE AND INTERNET EVENT

Join Us for Our Twentieth Year!

For Early Bird Registration Discount, Register by Friday, September 21!

CO-CHAIRS: **Sajida T. Dwyer, J.D.**, **Robert J. Dwyer, J.D.**, **Jeffrey M. Karam**, **Jessie M. Miller, J.D.**, **Sally Hedley, J.D.**

FEATURING A CO-CHAIR: **Sally Hedley, J.D.**

CONTINUING EDUCATION CREDITS: **16.00 CPE**

GOLD GRANTOR: **Deloitte.**

SILVER GRANTORS: **EY**, **INQVIA**

BRONZE GRANTORS: **AltoPartners**, **ankura**, **BRG**, **Cooley**, **COVINGTON**, **Cutting Edge**, **DEVA WRIGHT**, **NAVIGANT**, **HELIO**, **DEVA WRIGHT**, **NAVIGANT**, **KING & SPALDING**, **POZNANSKI**, **POTOMAC**, **HOPES & GRAY**, **SAI GLOBAL**, **SIDLEY**, **Skadden**

Agenda- Nov 6th

WEDNESDAY, NOVEMBER 6, 2019

PHARMA CONGRESS AGENDA DAY I

1:00 pm
Welcome and Introduction: PCF Co-Chairs
 **Sajata I. Doyal, JD**, Vice President, Health Care Compliance and Privacy, Pharmaceutical Group, Johnson & Johnson, Titusville, NJ (PCF Secretary)
 **Jeffrey M. Kwanick, MBA**, Deputy Chief Compliance Officer, Jazz Pharmaceuticals, Inc., Philadelphia, PA (PCF Chair)

 **Jennifer McGee, JD**, Vice President and Chief Compliance Officer, Otsuka America Pharmaceutical, Inc., Rockville, MD (PCF Treasurer)
 **Margaret Sparks, JD**, Associate Vice President, North America Ethics and Business Integrity, Sanofi US, Bridgewater, NJ (PCF Co-Chair)
 **Donna White, CSEP**, Vice President, Contracts and Compliance, Celis, USA, Cary, NC (PCF Co-Chair)
 **Joe Zimmerman**, Vice President and Chief Compliance Officer, US, Ferring Pharmaceuticals, Parsippany, NJ (PCF Co-Chair)

1:15 pm
20th Anniversary Dialogue: Lessons Learned from 20 Years of Pharma and Medical Device Investigations, Prosecutions, Ethics and Compliance
 **Douglas M. Lankier, JD**, Executive Vice President, General Counsel, Pfizer, Former Assistant US Attorney, Southern District of New York, US Department of Justice, New York, NY
 **Daniel Ronald Levinson, JD**, Former Inspector General, US Department of Health and Human Services, Former Inspector General, US General Services Administration, Former Chairman, US Meat Systems Protection Board, Former General Counsel, US Consumer Product Safety Commission, Washington, DC
 **Lori Quaiser**, Senior Vice President and Global Chief Compliance Officer, Tere Pharmaceuticals, Former Senior Vice President, Global Compliance and Business Practices, Schering-Plough Corporation, Former Vice President, Chief Compliance Officer, Eli Lilly, Former Member, PCF Executive Committee, Horsham, PA
 **Arjun Rajaratnam, JD, MS**, Chief Compliance Officer, Smith & Nephew, Former Compliance Officer, US Pharmaceuticals, GlaxoSmithKline, Former Member, PCF Executive Committee, Raleigh, NC
 **James Sheehan, JD**, Chief, Charities Bureau, New York State Department of Law (Attorney General), Former Chief Integrity Officer, Executive Deputy Commissioner, City of New York Human Resources Administration, Former NY Medical Inspector General, Former Associate Chief State Attorney, US Attorney's Office for the Eastern District of Pennsylvania, New York, NY
 **Susan Winkler, JD**, Partner, Pinerio Rindridge, Former Assistant US Attorney and Head, Health Care Fraud Unit, US Attorney's Office for the District of Massachusetts, Boston, MA
 **Kris Curry, MBA**, Principal, Account Services, ET, Former Vice President, Global Chief Compliance Officer, Pharma Sector, Johnson & Johnson, Philadelphia, PA (Moderator)

2:15 pm
Keynote: OIG Update
 **Mary E. Riordan, JD**, Senior Counsel, Office of Counsel to the Inspector General, Office of Inspector General, Department of Health and Human Services, Washington, DC

3:00 pm
US DOJ Keynote
 **Brian Allen Benczkowski, JD**, Assistant Attorney General, Criminal Division, US Department of Justice, Former Principal Deputy Assistant Attorney General for Legislative Affairs, Former Republican Staff Director, Committee on the Judiciary, US Senate, Former Staff, Senator Pete Domenici and Representative Jim Sensenbrenner, Washington, DC

3:30 pm
Break

4:00 pm
FDA Keynote
 **Thomas W. Abrams, RPh, MBA**, Director, Office of Prescription Drug Promotion, US Food and Drug Administration, Silver Spring, MD

4:30 pm
What Pharma/Medical Device Industries Can Learn from the Opioid Cases
 **Richard Heilig, JD**, First Assistant US Attorney, US Attorney's Office, District of New Jersey, US Department of Justice, Former Corporate Counsel, Litigation, Colgate, New York, NY
 **John C. Richter, JD**, Partner, King & Spalding, Former Acting Assistant Attorney General, Criminal Division, US Department of Justice, Former US Attorney, Western District of Oklahoma, Washington, DC

5:00 pm
Annual Chief Compliance Officer Roundtable
 **Charlene E. Davis, JD**, Associate Vice President and Head of Healthcare Compliance North America, Sun Pharmaceutical Industries, Inc., Former Senior Compliance Counsel and Senior Director, Corporate Compliance and Compliance Operations, Otsuka Pharmaceutical, Princeton, NJ
 **Adam Debow, JD**, Global Chief Compliance and Ethics Officer, Bristol Myers Squibb, Princeton, NJ
 **Kath Kereschuk, MPh, JD**, Vice President and Chief Compliance Officer, Dunster Diagnostics and Beckman Coulter Diagnostics, DDMERK Corporation, Former Partner, Arnold & Porter Agyn Schkies, Chevy Chase, MD
 **Dominique Laymond, Esq.**, Executive Vice President, Chief Ethics and Compliance Officer, Quest Diagnostics, International Society of Healthcare Ethics and Compliance Professionals (ISHCEP), Paris, France
 **Saritha Ramamurthy, JD**, Head of Compliance, Law Oncology, wholly owned subsidiary of US Lilly, Former Executive Director, Office of Ethics and Compliance, Boehringer Ingelheim Pharmaceuticals, Stamford, CT
 **Paul Silver**, Principal, Regulatory & Compliance Life Sciences Leader, Deloitte Advisory, Deloitte & Touche LLP, Atlanta, GA (Moderator)

6:00 pm
ADJOURNMENT AND NETWORKING RECEPTION AND 20TH ANNIVERSARY PARTY

HOTEL INFORMATION/RESERVATIONS
 The Pharmaceutical and Medical Device Compliance Congress does not contract with any third party organization to make hotel reservations for attendees of the Congress. All attendees should make their hotel reservations directly with the hotel and not with a third party vendor.
 The Mandarin Oriental, Washington DC is the official hotel for the Seventeenth Annual Pharmaceutical and Medical Device Compliance Congress. A special group rate of \$200/night (before taxes) per night (two applicable state and local taxes) has been arranged for Congress attendees. To make reservations at the group rate, go to www.PharmaCongress.com and click on the "HOTELS/RTS" tab. You may also make reservations by calling the Mandarin Oriental directly at 202.224.4000 or 1-800-800-1070. Please ask for the "Pharmaceutical Congress Rate" when you call. Reservations at the group rate will be accepted while rooms are available or until the cut-off date of **Sunday, October 13, 2019**. After this date, reservations will be accepted on a space available basis at the prevailing rate.

1:15pm: Lessons learned from 20 years of Pharma and Med Device Investigations, Prosecutions, Ethics & Compliance

2:15pm: Keynote: OIG Update- Mary Riordan, JD

3:00pm: US DOJ Keynote: Brian Allen Benczkowski, JD

3:15pm: Break

4:00pm: FDA Keynote: Tom Abrams, RPh, MBA

4:30pm: What Pharma/Med Device Can Learn from Opioid Cases

5:00pm: Annual Chief Compliance Officer Roundtable

<http://www.pharmacomplianceforum.org/>

DOWNLOAD THE CONFERENCE APP ON YOUR MOBILE DEVICE!

Scan the QR code located on the cover of your agenda to download the 20th Annual Pharmaceutical and Medical Device Compliance Congress official Event App for iPhone or Android.

After the app is installed, please Sign Up and setup your Profile!

Tip: Use your LinkedIn profile. Go the Events Tab and select Search for an Event.

After signing up, search for 20th Annual Pharmaceutical and Medical Device Compliance Congress.

Select Join Now and use the Passphrase PHARMA20

Ask A Question

In the Conference App, swipe to the **Polls and Q&A button.**

At the top of the screen choose **Q&A**
Type your question in the box and select send.

You may choose to submit your questions anonymously
or include your name.

Conference App Tips

- Use your LinkedIn account to set up your profile
- The passphrase is *Pharma20*
- This passphrase works for the *app*, the *question forum* and the *polls*
- Save the sessions you would like to attend to your schedule
- Select Attendees to network with your colleagues

Instructions for Accessing the Live Polling

In the Conference App, swipe to the **Polls and Q&A button**. At the top of the screen choose **Polls**.

Or open your Browser and go to **Sli.do**

Enter the code: **Pharma20**

Tap **Polls** at the top of the screen. The poll will be on the screen.

How many Pharma/Med Device Compliance Congresses have you attended?

1. This is my first Congress
2. 2-4
3. 5-7
4. 8-12
5. 13-19
6. All 20 years! Do I get a prize?

What is your current role?

1. In-house Compliance
2. In-house Legal
3. In-house Finance, Audit
4. Clinical, Medical Affairs or Regulatory
5. Government Employee
6. Outside Legal Counsel
7. Outside Consulting Firm
8. Other