

***WELCOME***

# **19th Annual Pharmaceutical and Medical Device Compliance Congress**

**MANDARIN ORIENTAL • WASHINGTON, DC**

**NOVEMBER 7 - 9, 2018**



# Nineteenth Annual Pharmaceutical and Medical Device Compliance Congress



**Jeffrey M. Kawalek, MBA**

Senior Director, Ethics & Compliance, North America,  
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Vice President and Chief Compliance Officer  
Otsuka America Pharmaceutical, Inc.



**Michael Clarke, JD**

Vice President, Corporate Compliance  
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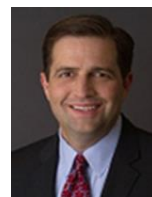
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Vice President,  
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**Margaret Sparks, JD**

Associate Vice President  
North America Ethics & Business Integrity  
Sanofi US



**Joe Zimmerman**

Vice President, Chief Compliance Officer  
Ferring Pharmaceuticals, Inc.



**Debra Scanlon (Deb)**

PCF Administration



# The Pharmaceutical Compliance Forum



The Pharmaceutical Compliance Forum is a not-for-profit trade association of compliance professionals and legal counsel from 70+ distinguished research-based pharmaceutical manufacturers and biotech companies.

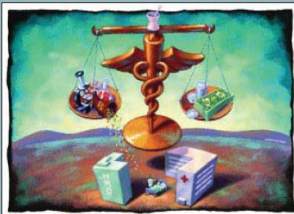
*Our members meet several times a year in an informal and open setting to discuss:*

- *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/>

# The First Annual Pharmaceutical Industry Regulatory & Compliance Summit



## Featured Speakers:

John Bertinoglio, Esq., Partner, Arnold & Porter and Former Associate Deputy Attorney General and Special Counsel for Health Care Fraud, Department of Justice

William McConigh, Esq., Associate Chief Counsel, US Food and Drug Administration, Office of the Chief Counsel

Carolyn J. McElroy, Director, Maryland Medicaid Fraud Control Unit

Lewis Morris, Assistant Inspector General for Legal Affairs, Office of the Inspector General in the US Department of Health and Human Services

Arvin P. Schroll, Ph.D., Arvin Schroll Associate and Former Deputy Director, Office of Enforcement, Food and Drug Administration

James Sheehan, Esq., Assistant US Attorney and Chief of the Civil Division, US Attorney's Office for the Eastern District of Pennsylvania

Loretta Suga, Resident Agent in Charge, FDA's Office of Criminal Investigations

## Participating Pharmaceutical

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

Co-Sponsored by:  
Health Care Compliance Association



In association with the  
Food and Drug Law Institute



and Medical Education Collaborative  
A Nonprofit Education Organization

2000

135

individuals Attendees

68 Pharmaceutical Company Attendees  
representing 28 different companies

67 Industry Attendees:

- 1 Academic Institution
- 5 Government Agencies
- 8 Law firms
- 3 Industry Associations
- 25 Industry Partners
- 6 Press

Apx

450

individuals Attendees

205 Pharmaceutical AND  
Medical Device Attendees

245 Industry Attendees:

- 3 Academic Institutions
- 13 Government Agencies
- 27 Law Firms
- 3 Industry Associations
- 17 Industry Partners
- 4 Press

A HYBRID CONFERENCE AND INTERNET EVENT

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

www.PharmCongress.com

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

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COMPLIANCE  
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**CO-CHAIRS:**  
Michael B. Clarke, JD, Vice President, Corporate Compliance, Johnson & Johnson (PCT Co-Chair)



Sujata T. Doyal, JD, Vice President, Health Care Compliance and Privacy, Pharmaceuticals Group, Johnson & Johnson (PCT Secretary)



Jeffrey M. Kowalik, MBA, Senior Director, Ethics and Compliance, North America, Bayer Pharmaceuticals, Inc. (PCT Co-Chair)



Jennifer McGee, JD, Vice President and Chief Compliance Officer, Oculars America Pharmaceutical, Inc. (PCT Treasurer)



Margaret Sparks, JD, Associate Vice President, North America Ethics and Business Integrity, Sanofi US (PCT Co-Chair)



Joe Zimmerman, Vice President and Chief Compliance Officer US, Forting Pharmaceuticals (PCT Co-Chair)



Richard E. Binstrom, MA, Chief Executive Officer, Front Line Anti-Bribery (UK), Combustion Ethics (FOTI Blog)



Zachary A. Conba, JD, Assistant US Attorney and Chief, Civil Division, US Attorney's Office, District of Rhode Island, US DOJ



Susan Dentzer, President and Chief Executive Officer, NEH; Analyst on Health Policy, The Brookings Senior Editor, Health Affairs



Jacob Elberg, JD, Assistant US Attorney US Attorney's Office, District of New Jersey, US DOJ



Christopher B. Harwood, JD, Assistant US Attorney and Chief, Civil Health Care Fraud Unit, US Attorney's Office, Southern District of New York, US DOJ



Tara Hallow, JD, Assistant Chief, FOTI Unit, Fraud Section, Criminal Division, US DOJ



Richard Henley, JD, First Assistant US Attorney, US Attorney's Office for the District of New Jersey, US DOJ



Mary E. Hordan, JD, Senior Counsel, Office of General In-Inspector General, US OIGHS



Gregg Shapiro, JD, Assistant US Attorney, US Attorney's Office, District of Massachusetts, US DOJ



Sally Q. Yates, JD, Partner, King & Spalding Former Acting Attorney General, Former Deputy Attorney General, US DOJ



Leticia Buckner, MA, Superior Special Agent and Unit Chief, International Compliance Unit, FBI



Richard E. Binstrom, MA, Chief Executive Officer, Front Line Anti-Bribery (UK), Combustion Ethics (FOTI Blog)



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# Nineteenth Annual Pharmaceutical and Medical Device Compliance Congress

*Wednesday, October 18th*

8:00 am	Welcome
8:00 – 8:30 am	<b>The OIG's Enforcement Initiatives in the Pharmaceutical Industry</b> <i>Lewis Morris, Assistant Inspector General for Legal Affairs, Office of the Inspector General in the US Department of Health and Human Services</i>
8:30 – 9:00 am	<b>State Enforcement Initiatives in the Pharmaceutical Industry</b> <i>Carolyn J. McElroy, Director, Maryland Medicaid Fraud Control Unit</i>
9:00 – 9:30 am	<b>A Federal Prosecutor's Perspective on the Pharmaceutical Industry</b> <i>James Sheehan, Esq., Assistant US Attorney and Chief of the Civil Division, US Attorney's Office for the Eastern District of Pennsylvania</i>
9:30 – 10:00 am	<b>Insights into the Department of Justice's Enforcement Initiatives</b> <i>John Bentivoglio, Esq., Partner, Arnold &amp; Porter and Former Associate Deputy Attorney General and Special Counsel for Health Care Fraud, Department of Justice</i>
10:00 – 10:30 am	<b>FDA Enforcement Initiatives</b> <i>Arvin P. Schroff, Ph.D., Arvin Schroff Associates and Former Deputy Director, Office of Enforcement, Food and Drug Administration</i>
10:30 – 11:00 am	<b>Regulator Q &amp; A</b> Questions and answers with the morning presenters.
11:00 – 11:30 am	Break

- OIG Keynote Address
- FDA Keynote Address
- AUSA Roundtable
- Qui Tam Roundtable
- DOJ, FBI and SEC FCPA Enforcement Update

2000

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11:00 – 11:30 am Break

11:30 am – 12:30 pm

CONCURRENT  
SESSIONS I

- A. **The Practical Implications of the Anti-Kickback Laws to Pharmaceutical Sales and Marketing**  
Joseph Metro, Esq., *Partner, Reed Smith Shaw & McClay*  
Douglas M. Lankler, Esq., *Counsel, Worldwide Corporate Compliance, Warner-Lambert Company*
- B. **Clinical Trials: Compliance Implications and Solutions**  
Larry McDade, Esq., *Office of Consumer Litigation, Department of Justice*  
Loretta Stipa, *Resident Agent-in-Charge, FDA's Office of Criminal Investigations*  
Claudia Baldassano, MD, *University of Pennsylvania*
- C. **Compliance on a Global Scale: How to Shape a Compliance Program for a Multinational Pharmaceutical Company**  
Bert Weinstein, Esq., *Vice President and Assistant General Counsel, Merck & Co., Inc.*  
Caroline West, Esq., *Vice President, Global Litigation and Compliance, Aventis Pharmaceuticals*
- D. **"Houston We Have a Problem" What to Do When the Feds Come Knocking**  
Mike Kendall, Esq. (Moderator), *Partner, McDermott, Will & Emery*  
Rick Robinson, Esq., *Partner, Fubright & Jaworski*  
Patricia Meador, Esq., *Partner, Womble, Carlyle Sandridge & Rice*

12:30 – 2:30 pm

Luncheon and Presentations

1:00 – 1:30 pm

**The Legal and Ethical Issues Raised by Advances in Genomics**

Barbara P. Fuller, JD, RHIA, *Senior Policy Advisor, National Human Genome Research Institute, National Institutes of Health*

1:30 – 2:30 pm

**Compliance Roundtable**

Eric Siegel, Esq., *Counsel, SmithKline Beecham*  
Valli Baldassano, Esq., *Director, Global Compliance, Pharmacia Corporation*  
Janice Forsyth, Esq., *Chief Compliance Officer, Express Scripts, Inc.*  
Douglas M. Lankler, Esq., *Counsel, Worldwide Corporate Compliance, Warner-Lambert Company*  
Brent L. Saunders, JD, MBA (Moderator), *Director, PricewaterhouseCoopers*

2:30 – 2:45 pm

Break

2:45 – 3:45 pm

CONCURRENT  
SESSIONS II

A. **Compliance with FDA Labeling and Advertising Requirements**

Louis Morris, Ph.D., *Senior Vice President, SCP Communications*  
Robert B. Nicholas, Esq., *Partner, McDermott, Will & Emery*

Mini Summit XII: The Fine Line of Promotion with Medical Professionals: Avoiding White Coat Marketing

Mini Summit XV: R&D: Hidden Risks beyond Clinical Trial Recruitment, including FMV, Invoicing

Mini Summit II: What's Old is New Again: Global Compliance Function Harmonization is Needed Now more than Ever

Mini Summit V: Dissecting Recent CIAs and Review of Draft Model CIA

FRIDAY, NOVEMBER 9, 2018

PHARMA CONGRESS: AGENDA DAY III

INDUSTRY-ONLY COMPLIANCE BEST PRACTICES  
THINK TANK

½ Day

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## *IN ADDITION TO.....*

- Promotion with Medical Professionals
- Avoiding **White Coat Marketing**
- **Market Access** Compliance Considerations
- Global Documentation Framework
- R&D: Hidden Risks beyond Clinical Trail Recruitment
- Compliance for **Small to Mid-size Pharma and Device** Companies
- Compliance Issues Associated with PBM Relationships
- **Risk Assessments and Mitigation Plans**
- “All in Compliance” — Aligning with Your **Business Partners**
- Navigating the Murky Waters of **Patient Programs**
- Compliance for “Evolved” Products
- Best Practice in **HCP/HCO Management**
- Compliance Considerations in **Value-based Contracting**
- Risks and Opportunities related to Medical Affairs
- An Interactive Case Study in Effective **Crisis Management**
- **Privacy** and **Cybersecurity Compliance** Update, including **GDPR**
- The Compliance Training Revolution
- Fostering a **Culture of Ethics** and Compliance
- **Global Compliance** Function Harmonization
- **Third Party** Lifecycle Management
- Annual Medical Device Compliance Roundtable
- Dissecting Recent **CIAs** and Review of Draft Model CIA
- Strategies to **Measure Effectiveness**, Monitor and Report
- Managing Promotional Programs and **Patient Advocacy Groups**
- **Open Payments**: Where Does the Sun Shine Now?
- Interactions with **Specialty Pharmacy**
- Is your **Board** Bored of your Compliance Dashboards?
- Next Generation **Data Analytics**

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## Download the Pharma Congress App

The **Pharma Congress App** has the

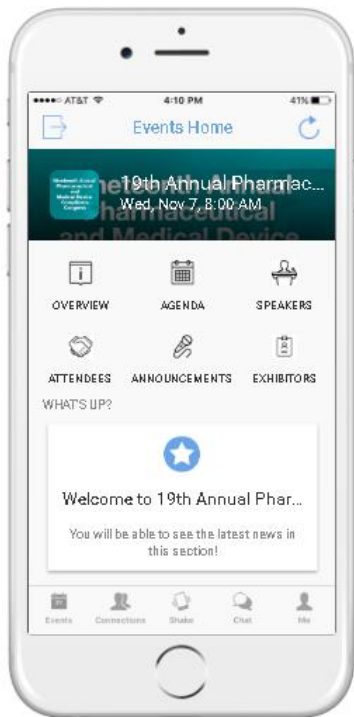
- schedule
- speaker bios
- presentations
- exhibitor information
- question forum

Access **live polling** via the app throughout the conference

Information on downloading the conference app can be found on the **cover of your conference agenda**



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## 19th Annual Pharmaceutical and Medical Device Compliance Congress

Download our official app:



 Scan QR Code

 Text me the Link

Download the app using  
the QR code  
on the cover of your agenda  
Passphrase: **Pharma2018**



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## Conference App Tips

- Use your LinkedIn account to set up your profile
- The passphrase is **Pharma2018**
- 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

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## Instructions for Asking a Question

In the Conference App:

- swipe to the **Ask a Question button**
  - Enter the code: **Pharma2018**
    - At the top of the screen choose **Questions**
      - Type your question in the box
        - Select **send**

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

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## Instructions for Accessing the Live Polling

### In the Conference App:

- swipe to the *Ask a Question button*
  - Enter the code: *Pharma2018*
    - At the top of the screen choose *Polls*

### On Your Own Device:

- open your Browser and go to *Sli.do*
  - Enter the code: *Pharma2018*
    - At the top of the screen choose *Polls*

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## 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

# Nineteenth Annual Pharmaceutical and Medical Device Compliance Congress

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

1. This is my first Congress
2. 2-3
3. 3-6
4. 7-11
5. 12-18
6. All 19 years!