Drug Quality and Security Act Conference
Skadden, Arps, Slate, Meagher & Flom LLP
1440 New York Ave, NW | Washington, DC 20005
November 15, 2017

AGENDA

8:30–9:15 AM **Registration and Continental Breakfast**

9:15–9:20 AM **Welcome and Opening Remarks** *(Room 11 A/B)*

Laura Brown, Director, Educational Programs, Food and Drug Law Institute
Karla L. Palmer, Director, Hyman, Phelps & McNamara, PC and Chair, Drug Quality and Security Act Conference

9:20–10:00 AM **Keynote Address - Title I (Compounding Quality Act) Implementation – Pharmacy Compounding in 2017** *(Room 11 A/B)*

Julie Dohm, Senior Science Advisor for Compounding, CDER, FDA
Introduced by **Karla L. Palmer**, Director, Hyman, Phelps & McNamara, PC and Chair, Drug Quality and Security Act Conference

10:00–10:40 AM **Keynote Address - Title II (Drug Supply Chain Security Act) Implementation Track and Trace Issues in 2017** *(Room 11 A/B)*

Ilisa Bernstein, Deputy Director, Office of Compliance CDER, FDA
Introduced by **Abraham Gitterman**, Associate, Arnold & Porter Kaye Scholer LLP

10:40–11:00 AM **Coffee and Networking Break**

11:00–12:00 PM **Concurrent Breakout Sessions**

Title I (CQA) – Industry Update: FDA's Significant Guidance Documents and Industry Actions/Reactions on Regulation of Compounding *(Room 11 A/B)*

In this breakout session, speakers will review FDA's guidance for traditional compounders and outsourcing facilities under sections 503A and 503B, their practical applicability, and effects on both types of entities.

A.J. Day, Director of Clinical Services, PCCA
Alexander Pytlarz, Owner/Director of Pharmacy Operations, The Compounding Center
Sara Rothman, Senior Policy Advisor, Office of Unapproved Drugs and Labeling Compliance, CDER, FDA
Lee Rosebush, Chairman, Outsourcing Facilities Association, and Partner, BakerHostetler

Moderated by **Elizabeth R. Jungman**, Director, Public Health Programs, The Pew Charitable Trusts

Title II (DSCSA) – Industry Update: Recent Developments and Unanswered Questions Concerning Implementation of the DSCSA *(Room 11-146)*

In this breakout session, speakers will discuss next steps in DSCSA implementation, including FDA guidance and regulatory developments and its effect on industry; the grandfather designation and product identifiers; FDA's working groups/case studies process; and lingering questions, such as the applicability of Title II to 503B repackaging facilities.

Scott Mooney, Vice President Distribution Operations - Supply Chain Assurance, McKesson Corporation
Anne Marie Polak, Senior Director, Leavitt Partners, LLC
Jennifer Zachary, Partner, Covington & Burling LLP
Moderated by **Abraham Gitterman**, Associate, Arnold & Porter Kaye Scholer LLP

12:00–1:30 PM **Luncheon Presentation:** DSCSA and Blockchain *(Room 11 A/B)*
Discussion of the utilization of blockchain as a possible way to address unresolved DSCSA data security issues.

Bob Celeste, Founder, Center for Supply Chain Studies
Introduced by **Jennifer Bragg**, Partner, Skadden, Arps, Slate, Meagher & Flom LLP and Member, FDLI Board of Directors

1:30–2:30 PM **Concurrent Breakout Sessions**

Title I – FDA and Inspections: What to Consider When FDA Visits Your Facility *(Room 11 A/B)*

Panelists will discuss FDA's inspection guidance, generally how to prepare for an inspection, what FDA may be looking for, and how to respond to Agency inquiries and observations.

Jennifer Bragg, Partner, Skadden, Arps, Slate, Meagher & Flom LLP and Member, FDLI Board of Directors
Andrew Harrison, Vice President, Legal & Compliance, PharMEDium Services, LLC
Ruey C. Ju, Acting Senior Advisor for Compounding and Enforcement, CDER, FDA

Title II – Licensure of Wholesale Distributors and 3PL's: Where does FDA Stand, Where do States Stand, What About VAWD, and What Can You do About It? *(Room 11-146)*

Speakers will discuss the hurdles to licensure on the state and federal level for wholesalers and distributors, and will attempt to provide some answers.

Elizabeth A. Gallenagh, Senior Vice President, Government Affairs and General Counsel, Healthcare Distribution Alliance
Lori F. Hirsch, Managing Counsel, Merck & Co., Inc.
Moderated by **Karla L. Palmer**, Director, Hyman, Phelps & McNamara, PC and Planning Committee Chair, Drug Quality and Security Act Conference

2:30–2:45 PM **Coffee and Networking Break**

2:45–3:45 PM **Concurrent Breakout Sessions**

Title I – Enhanced Enforcement Activity in the Compounding World *(Room 11 A/B)*

In this breakout session, speakers will explore recent enforcement activities by FDA, DOJ, and states involving compounding pharmacies and outsourcing facilities, including what FDA and states seem to consider when determining whether and how to pursue certain compounding practices.

Hube Dodd, Founder, The Dodd Law Firm
David J. Horowitz, Partner, Hogan Lovells LLP
Rachael Pontikes, Partner, Reed Smith LLP
Jeffrey Steger, Senior Counsel for Complex Litigation, Consumer Protection Branch, US Department of Justice

Title II – Serialization and Enforcement *(Room 11-146)*

Panelists will focus on product identifiers and verification, FDA's guidance delaying enforcement for one year, public meetings, and pilot projects. Suspect packaging reporting will also be addressed.

Brent G. Eilefson, Vice President, Legal Affairs, Upsher-Smith Laboratories, LLC
Justine Freisleben, Senior Director, Industry Relations, Healthcare Distribution Alliance
Connie Jung, Acting Associate Director for Policy and Communications, Office of Drug Security, Integrity, and Recalls, CDER, FDA
David Mason, AD Serialization ESO/Supply Chain, Sandoz
Chris Smith, Director, Federal Public Policy, National Association of Chain Drug Stores
Moderated by **William Garvin**, Shareholder, Buchanan Ingersoll & Rooney PC

3:45 PM **Conference Adjournment**