

# Life Sciences & Healthcare Industry Group



**FEB. 1, 2019**

For more information,  
contact:

Krishna Kavi  
+1 202 626 8972  
[kkavi@kslaw.com](mailto:kkavi@kslaw.com)

Cassandra Rasmussen  
+1 202 626 9127  
[crasmussen@kslaw.com](mailto:crasmussen@kslaw.com)

---

## King & Spalding

Washington, D.C.  
1700 Pennsylvania Ave., NW  
Washington, D.C. 20006-  
4707  
Tel: +1 202 737 0500

## Selected Takeaways From King & Spalding's 11th Annual Pharmaceutical University

More than 320 representatives from more than 120 pharmaceutical and biotechnology companies attended King & Spalding's 11th Annual Pharmaceutical University in Philadelphia last November. The 2018 curriculum was compelling and substantively diverse, with four concurrent tracks and 24 different interactive presentations from which attendees could choose. The full agenda can be found [here](#). In a well-received innovation this year, we dedicated one full track (six sessions) to pharmaceutical law fundamentals to appeal to lawyers new to the industry and to provide a refresh for veterans. Our 63 K&S presenters addressed regulatory, enforcement, litigation, commercial, corporate, intellectual property, international trade and political issues, among other topics. Below are some key takeaways from selected sessions. *Click [here](#) to learn more about our Life Sciences and Healthcare Industry Group and [register here](#) to receive related firm publications.*

### **Pharma in the Crosshairs – Congressional Oversight in 116<sup>th</sup>**

**Congress:** The panelists presented an analysis of the key congressional oversight committees, explained their legal authorities, and highlighted how recent pharmaceutical-focused inquiries such as the Mylan Epi-Pen investigations will shape investigations in the 116<sup>th</sup> Congress. *Panelists: Ted Hester, Dan Donovan, and William Clarkson. Click [here](#) for slides.*

### **FDA Advertising and Promotion Update: Exploring Key Developments in Pharmaceutical Communications in 2018 and Beyond:**

While enforcement letters from FDA's Office of Prescription Drug Promotion remained relatively low in 2018, the panelists identified some key trends: boxed warning products were top targets, conference booths are still an area of focus, corporate websites may be new targets, and estrogen drugs are facing increased scrutiny. *Panelists: Nikki Reeves, Heather Bañuelos and Gillian Russell. Click [here](#) for slides.*



---

**Tilting at Windmills? Pharmaceutical Enforcement Developments and Trends in 2018:** the speakers highlighted the current enforcement climate, the impact on enforcement due to recent DOJ changes, core theories and new theories of liability, and compliance, litigation, and risk strategies. Panelists also provided an overview of key DOJ settlement dynamics, including DOJ aversion to bad precedent, obstacles to denial-type language in settlement agreements, and settlements calculated to generate headlines. *Panelists: Mark Jensen, Brandt Leibe and Patrick Otlewski. Click [here](#) for slides.*

**Service Fees to Channel Partners: Understanding Anti-Kickback, Pricing, and Enforcement Risks:** the speakers discussed potential enforcement risks related to fees paid for administrative services to channel intermediaries (e.g., PBMs, SPs, GPOs and IDNs, among others) and provided recommendations and best practices to mitigate such risks. *Panelists: John Richter, John Shakow and Seth Lundy. Click [here](#) for slides.*

**Guarding Against and Responding to Trade Secret Theft: A Primer:** The panelists examined different kinds of threats (internal and external) and the common means and motivations behind cyberattacks. Trade secrets, they said, “may be the most vulnerable type of intellectual property.” *Panelists: Michael Johnston, John Horn, and Chris Burris. Click [here](#) for slides.*

**Products Liability Highs and Lows: Developments and Trends Over the Past Year:** The presenters discussed recent trends in FDA preemption, questions of personal jurisdiction, multi-plaintiff trials, and the “good company defense.” The presentation delved into analyses of key cases in each of these areas. Some highs and lows are to be expected, but there are defense tactics to help avoid un-level playing fields. *Panelists: Mark Brown, Bruce Hurley, and Lana Varney. Click [here](#) for slides.*

**Strategic Equity Investments – 10 Questions You Should Ask Before You Invest:** The presenters discussed, among other key considerations, the importance of assessing the purpose and means of the investment, which rights should be maintained in the investment, the types of events that could affect the investment, how the investment might come with its own limitations, how to get out of the investment if necessary, and whether an investment makes sense for a company. With each question, the presenters offered tools for assessing investors’ answers. *Panelists: Enrico Granata and Ted Keim. Click [here](#) for slides.*

**Staying On Top Of Your Game: Strategies to Defend Pharma Patents Against Generics’ and Biosimilars Challengers’ Trending Tricks:** This session covered some common tricks in pharma patent litigation, such as attempting “design-around” products. Other highlighted “tricks” included: using claim construction to score early points, using multiple conflicting defenses to “squeeze” the patentee, challenging patents in multiple venues simultaneously, and gaming the biosimilars “patent dance.” *Panelists: Gerald Flattmann, Evan Diamond, and Vanessa Yen. Click [here](#) for slides.*

*[Krishna Kavi](#) and [Cassie Rasmussen](#) are Washington, D.C.-based associates in King & Spalding’s Life Sciences & Healthcare Industry Group.*

---

## ABOUT KING & SPALDING



---

Celebrating more than 130 years of service, King & Spalding is an international law firm that represents a broad array of clients, including half of the Fortune Global 100, with 1,000 lawyers in 20 offices in the United States, Europe, the Middle East and Asia. The firm has handled matters in over 160 countries on six continents and is consistently recognized for the results it obtains, uncompromising commitment to quality, and dedication to understanding the business and culture of its clients.

This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice. In some jurisdictions, this may be considered "Attorney Advertising."

ABU DHABI	CHICAGO	HOUSTON	NEW YORK	SILICON VALLEY
ATLANTA	DUBAI	LONDON	PARIS	SINGAPORE
AUSTIN	FRANKFURT	LOS ANGELES	RIYADH	TOKYO
CHARLOTTE	GENEVA	MOSCOW	SAN FRANCISCO	WASHINGTON, D.C.

---