



## **Food and Drug Law Journal 2020 Symposium**

**This Teachable Moment: How COVID-19 Provides Lessons from FDA's Past and Present That Will Benefit Its Future Preparedness**

November 12–13, 2020

Virtual Event

### **Agenda**

#### **THURSDAY, NOVEMBER 12, 2020**

##### **12:00–12:15 PM Welcome Announcements**

**Amy Comstock Rick**, President & CEO, FDLI

**Paige Samson**, Director, Innovative Programs and Publications, FDLI

##### **12:15–12:45 PM Keynote Address**

**Dr. Anand Shah**, Deputy Commissioner for Medical and Scientific Affairs, Office of the Commissioner, FDA

**Lowell Zeta**, Senior Counselor to the Commissioner, Office of the Commissioner, FDA

##### **12:45–12:50 PM Break**

##### **12:50–2:20 PM Paper Presentations**

**Topic:** **“History, Legislative Innovation, and Future Pandemics”**

**Daniel A. Kracov**, Arnold & Porter and Vice Chair, FDLI Board of Directors

**Topic:** **“Agencies Unbound: How COVID-19 Prompted Regulatory Flexibility and How to Build on it for the Future”**

**Brian D. Eyink**, **Elizabeth B. Fawell**, **Steven B. Steinborn**, and **Anneke Baran Altieri**, Hogan Lovells US LLP

**Moderator:** **Laurie Beyranevand**, Vermont Law School

**Discussant:** **Kalah Auchincloss**, Greenleaf Health, Inc.

##### **2:20–2:30 PM Break**

##### **2:30–3:15 PM Paper Presentation**

**Topic:** **“The American Pharmaceutical Supply Chain: Will COVID-19 Drive Manufacturing Back Home?”**

**Gregory H. Levine**, **Jenna McCarthy\***, and **Beth P. Weinman**, Ropes & Gray LLP and Grant Sims\*, NYU Stern School of Business

**Moderator:** **Marian J. Lee**, Gibson, Dunn & Crutcher LLP



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**Discussant:** **Ralph F. Hall**, University of Minnesota Law School and Leavitt Partners, LLC

**3:15–3:30 PM**      **Break**

**3:30–5:00 PM**      **Paper Presentations**

**Topic:**      **“Vaccine-Related Liability: Past Approaches, Current Challenges, and Proposals for Encouraging Future Innovation and More Widespread Vaccine Use”**

**Camille L. Fletcher, Greg Margolis\***, and **John D. Winter**, Patterson, Belknap, Webb & Tyler LLP

**Topic:**      **“A Test of the Emergency (Use Authorization) System: Challenges in FDA Regulation of COVID-19 Diagnostics”**

**Jeffrey N. Gibbs**, and **Gail H. Javitt\***, Hyman, Phelps & McNamara, P.C.

**Moderator:** **James T. O’Reilly**, University of Cincinnati, and Chair, *Food and Drug Law Journal* Editorial Advisory Board

**Discussant:** **J.R. McNair**, Winston & Strawn LLP

**5:00–5:30 PM**      **Networking Event**

## **FRIDAY, NOVEMBER 13, 2020**

**12:00 PM**      **Welcome Remarks**

**Sonia L. Canzater**, Senior Associate, Hepatitis Policy Project, O’Neill Institute for National and Global Health Law, Georgetown University Law Center

**Paige Samson**, Director, Innovative Programs and Publications, FDLI

**12:00–1:30 PM**      **Paper Presentations**

**Topic:**      **“How We Got Here: FDA Emergency Use Authorization from 9/11 to COVID-19”**

**Jonathan Iwry**, Harvard Law School

**Topic:**      **“Assessing COVID-19 Emergency Use Authorizations”**



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**Efthimios Parasidis, Patricia J. Zettler\***, and **Micah Berman\***, The Ohio State University

**Moderator:** **Joseph Page**, Georgetown University

**Discussant:** **Nathan A. Brown**, Akin Gump Strauss Hauer & Feld LLP

**1:30–1:45 PM**      **Break**

**1:45–2:30 PM**      **Paper Presentation**

**Topic:**      **“One Health Pandemic Prevention and Mitigation: The Role of FDA”**  
**Margaret Foster Riley**, University of Virginia, and Member, FDLI Board of Directors

**Discussants:** **Bernadette Dunham**, Milken Institute School of Public Health, George Washington University and Advisor to the FDA One Health Initiative, Center for Veterinary Medicine, FDA  
**Capt. Brianna Skinner**, Office of the Commissioner, Office of Counterterrorism and Emerging Threats, FDA

**2:30–2:45 PM**      **Break**

**2:45–4:15 PM**      **Paper Presentations**

**Topic:**      **“Federal Law’s Protective Quilt: Understanding the Statutory Regimes for Personal Protective Equipment (PPE) and Recommending an Additional Piece”**  
**John F. Johnson III**, Shook, Hardy & Bacon LLP

**Topic:**      **“Regulatory Reactivity: FDA and the Response to COVID-19”**  
**Yaniv Heled**, Georgia State College of Law  
**Ana Santos Rutschman**, St. Louis University School of Law  
**Liza Vertinsky**, Emory University School of Law

**Discussants:** **Lewis Grossman**, American University  
**Alan G. Minsk**, Arnall Golden Gregory LLP  
**Carolina M. Wirth**, Arnall Golden Gregory LLP