

**WIET LIFE SCIENCE LAW SCHOLARS CONFERENCE
LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW
FRIDAY, SEPTEMBER 10, 2021
VIA ZOOM**

AGENDA

9:15-9:30am: Welcome & Introductions

9:30am: *Pharmaceutical Patents and Adversarial Examination*

Author: Dmitry Karshedt, Associate Professor of Law, George Washington University Law School

Commentators:

- Melissa Wasserman, Charles Tilford McCormick Professor of Law, University of Texas at Austin School of Law
- Josh Sarnoff, Professor of Law, DePaul University College of Law

10:30am: *Evidence-Based Regulation of Off-Label Information*

Author: David A. Simon, Research Fellow, Digital Home Health, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard University Law School

Commentators:

- Cynthia Ho, Clifford E. Vickrey Research Professor and Director, Intellectual Property Program, Loyola University Chicago School of Law
- Charlotte Tschider, Assistant Professor of Law, Loyola University Chicago School of Law

11:30am – 12:00 Lunch

12:00pm: *Fostering Innovation and Ensuring Safety A Pilot Empirical Study of the FDA's 510(k) Pathway*

Author: George Horvath, Assistant Professor of Law, University of Akron School of Law

Commentators:

- Megan Wright, Assistant Professor of Law, Medicine, and Sociology, Pennsylvania State University Law School
- Jordan Paradise, Georgia Reithal Professor of Law and Co-Director, Beazley Institute for Health Law & Policy, Loyola University Chicago School of Law

1:00pm: *Costly Gadgets: Barriers to Market Entry and Price Competition for Generic Drug-Device Combinations in the United States*

Author: Michael Sinha, Regulatory Science Fellow, Harvard-MIT Center for Regulatory Science, Program in Therapeutic Science (HiTS), Harvard Medical School.

Commentators:

- Kevin Outterson, N. Neal Pike Scholar in Health and Disability Law and Executive Director of CARB-X, Boston University School of Law
- Sam Halabi, Senior Associate Vice-President for Health Policy & Ethics; Professor, Colorado School of Public Health and Department of Political Science, College of Liberal Arts, Colorado State University

2:00-2:15: Break

2:15pm: *Normalizing Reproductive Genetic Modification*

Author: Myrisha Lewis, Associate Professor of Law, William & Mary Law School

Commentators:

- Seema Mohapatra, Murray Visiting Professor of Law, SMU Dedman School of Law
- Stacey Tovino, Professor of Law, University of Oklahoma College of Law

3:15pm: Closing Remarks