

AGENDA

Note: All lectures Monday-Friday will take place in Hotung Room 1000.

MONDAY, JULY 14, 2014: INTRODUCTION TO THE NATIONAL AND INTERNATIONAL REGULATION OF THE FOOD AND DRUG SUPPLY

9:00 AM-9:30 AM	REGISTRATION AND WELCOME BREAKFAST
9:30 AM-11:00 AM	WELCOME AND INTRODUCTION <ul style="list-style-type: none">• Welcome to the O'Neill Institute• Introduction of participants• Opening lecture SPEAKER <ul style="list-style-type: none">• Nan Hunter, <i>Associate Dean for Graduate Programs and Professor of Law, Georgetown University Law Center</i>• Sam Halabi, <i>Associate Professor of Law, The University of Tulsa College of Law and Scholar, O'Neill Institute</i>
11:00 AM-11:15 AM	COFFEE BREAK
11:15 AM-12:45 PM	CHALLENGES AND OPPORTUNITIES IN CHANGING FOOD AND DRUG SUPPLY CHAINS, RESEARCH, PUBLIC HEALTH AND REGULATION <ul style="list-style-type: none">• Food and Drug Law Governance: Industry, the Academy, Government and Global Health Advocacy Organizations• Medical Product Safety and Security Across the Global Manufacturing Supply Chain• Big Data and the Reorientation of Drug Regulation• The Human Microbiome and the Future of Drugs for Non-communicable Diseases• Regulation in the Face of Antimicrobial Resistance SPEAKERS <ul style="list-style-type: none">• Jesse L. Goodman, <i>Former Chief Scientist, FDA and Director, Georgetown University Center on Medical Product Access, Safety and Stewardship</i>• Sandra Eskin, <i>Director, Food Safety, The Pew Charitable Trusts</i>• Moderator: <i>Sam Halabi, Scholar, O'Neill Institute</i>
12:45 PM-2:45 PM	LUNCH

2:45 PM-3:45 PM

CURRENT TRENDS IN THE ARCHITECTURE AND ENFORCEMENT OF US FEDERAL FOOD AND DRUG LAW

This panel will provide an overview of the core federal statutes regulating food and drug safety as well as trends in civil and criminal enforcement actions, including the:

- The Federal Food, Drug and Cosmetics Act and Recent Additions and Revisions
- The Federal False Claims Act and Trends in Off-Label Marketing Enforcement
- The Park Doctrine and Criminal Enforcement of FDCA Regulations

SPEAKERS

- Joseph Page, *Professor of Law, Georgetown University Law Center; Director, Center for the Advancement of the Rule of Law in the Americas*
- Ariel Glasner, *Associate, Blank Rome LLP*
- Jodi Avergun, *Partner, Cadwalader, Wickersham & Taft LLP*
- Moderator: Aliza Glasner, *Institute Associate, O'Neill Institute*

3:45 PM-4:00 PM

BREAK

4:00 PM-5:00 PM

ROUNDTABLE ON NON-US APPROACHES TO FOOD AND DRUG REGULATION

This session features participants from African Union Member Countries, Brazil, Canada, China, EU Member Countries, India, Korea and Mexico and what the regulatory infrastructure looks like in these jurisdictions as well as the role of advocates, regulators, and industry participants in the regulatory regime. This interactive discussion forum will examine comparative theories of regulation, including those relating to correction of market failures, paternalism, and the practicalities of interacting with regulators in comparative context.

SPEAKER

- Sam Halabi, *Scholar, O'Neill Institute*
-

TUESDAY, JULY 15, 2014: BEST PRACTICES

Day 2 will focus on current trends in the best practices of manufacturing processes, doing business in foreign jurisdictions, and attending to regulatory regimes based not just from FDA, but from the FTC and the EPA as well.

9:30 AM-11:00 AM

Before the FDA Comes Knocking: Current Good Manufacturing Practices and Dealing with FDA Enforcement Actions

This session will examine:

- Best practices in manufacturing quality control
- FDA Enforcement Actions: Investigation, Communication and Execution
- Best practices in light of recent legislative and regulatory changes

SPEAKERS

- Jennifer Zachary, *Partner, Food and Drug Practice Group, Covington and Burling, LLP*
- Marc Scheineson, *Partner, Chair, Food and Drug Law Practice Group, Alston and Bird, LLP*
- Moderator: Sam Halabi, *Scholar, O'Neill Institute*

11:00 AM-11:15 AM

COFFEE BREAK

11:15 AM-12:45 PM

FOOD AND DRUG REGULATION IN SHARE REGULATORY SPACE: PERSPECTIVES FROM THE FEDERAL TRADE COMMISSION AND ENVIRONMENTAL PROTECTION AGENCY

This session will examine:

- FTC authority over food and nutrition advertising including deceptive acts or practices and “materiality” standards for food and nutrient claims
- Coordination between FTC and USDA or FDA over food and drug claims
- Relationship between regulatory enforcement actions and private litigation to enforce accurate labeling standards
- EPA policies toward food safety especially agricultural policy
- EPA’s International Partnerships with Codex Alimentarius, OECD and NAFTA

SPEAKERS

- David Vladeck, *Professor of Law, Georgetown University Law Center; Former Director of FTC’s Bureau of Consumer Protection*
- Lisa Heinzerling, *Professor of Law, Georgetown University Law Center; Former Associate Administrator, EPA Office of Policy*
- Moderator: Sam Halabi, *Scholar, O'Neill Institute*

12:45 PM-2:15 PM

LUNCH

2:15 PM-4:00 PM

BEST PRACTICES IN REGULATORY COMPLIANCE AND THE INTERFACE OF MANUFACTURING, SUPPLY CHAINS AND STANDARDS IN CHINA

This panel will examine:

- Best practices in establishing and maintaining pharmaceutical, medical device, health care, and other operations in China
- Clearing regulatory hurdles and navigating China's legal and business environment
- Standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements
- Fraud, reimbursement, and off-label enforcement trends
- Linkages between reimbursement, import-export, and quality control measures

SPEAKERS

- Philip Chen, *Assistant General Counsel, Office of the US Trade Representative*
- Gordon Schatz, *Asia Integration Partner, Life Sciences Health Industry Group, Reed Smith, LLP*
- Ed Zhao, *Vice President, Global Education and Training, U.S. Pharmacopeial Convention (USP)*
- Moderator: Susan Roosevelt Weld, *Executive Director, Law Asia Leadership, Adjunct Professor of Law, Georgetown University Law Center*

4:00 PM-4:30 PM

BREAK

4:30 PM-5:30 PM

KEYNOTE: DR. MARGARET HAMBURG

This keynote will focus on:

- The changing nature of FDA's consumer protection role as its activities expand overseas from raw materials and other ingredients to manufacture, storage, sale, and distribution
- International cooperation between regulatory agencies
- Challenges facing the FDA as emerging markets and developing countries contribute greater supplies of generic and new drugs
- Balancing prevention and inspection as regulatory strategies
- Data-driven risk analytics

SPEAKERS

- Margaret Hamburg, *US Food and Drug Administration Commissioner*
 - Moderator: John Monahan, *Senior Advisor to the President for Global Health and Senior Fellow, McCourt School of Public Policy, Georgetown University; Former Counselor to the Secretary and Director, Office of Global Health Affairs, US Department of Health and Human Services (HHS)*
-

5:30 PM-7:30PM

WELCOME RECEPTION
(HELD UPSTAIRS IN HOTUNG ROOM 2001)

WEDNESDAY, JULY 16, 2014: PUBLIC SECTOR AND PRIVATE SECTOR REGULATORY STRATEGIES

Day 3 will examine current trends in private, industry-driven regulatory initiatives as complements and alternatives to command and control, performance based or incentive based regulation accomplished through legislation and administrative action.

9:30 AM-11:00 AM

THE BALANCE BETWEEN REGULATION AND PRIVATE SECTOR INITIATIVE IN SECURING HEALTH SUSTAINABLE FOOD

This session will examine:

- Market pressure to reduce salt, sugar, and saturated fat content of processed food
- Supply chain management for fresh fruits, vegetable, and dairy
- Governance structures between industry and government with respect to managing non-communicable diseases through food content regulation

SPEAKER

- Derek Yach, *Senior Vice President, The Vitality Group, Former Senior Vice President of Global Health and Agriculture Policy at PepsiCo, Former Representative of the Director-General of the World Health Organization*

11:00 AM-11:15 AM

COFFEE BREAK

11:15 AM-12:45 PM

THE FDA'S GLOBAL REGULATORY ACTIVITIES

The panel will analyze:

- FDA's Global Regulatory Operations and Policy Directorate
- Globalization and the challenges and opportunities the Agency faces
- Going forward, the strategies GO is implementing to address these challenges

SPEAKERS

- Doug Stearn, *Deputy Director Policy and Analysis, US Food and Drug Administration*
- Jennifer Devine, *Deputy Director, Global Regulatory Operations and Policy, US Food and Drug Administration*

12:45 PM-1:15 PM

LUNCH

1:15 PM-3:15 PM

COUNTERFEIT MEDICINES, SAFE ONLINE PHARMACIES AND DETECTION TECHNOLOGIES

This session will engage participants in an interactive exercise that explores:

- Trends in the sale of counterfeit and substandard medicines through third-party and internet based vendors
- CD3 Detection Technology and its use at import sites, international postal facilities, and remote areas of the developing world.

SPEAKERS

- Jeff Gren, *Board Member, Alliance for Safe Online Pharmacies; President, Gren International Health & Trade Consulting; and Former Director, U.S. Department of Commerce, Office of Health and Information Technology*
- Ilisa Bernstein, *Deputy Director, Office of Compliance, Center for Drug Evaluation and Research, U.S. Food and Drug Administration*

3:15 PM-3:30 PM

BREAK

3:30 PM-5:00 PM

COMPARATIVE EU AND US APPROACHES TO FOOD AND DRUG REGULATION

This panel will focus on:

- Differences in regulatory communication and approval processes between US FDA and EU EMA
- Norms in interacting with US and European regulatory authorities
- Comparative approaches to risk assessment and analysis
- Mutual cooperation and recognition after the TTIP

SPEAKERS

- J. Benneville (Ben) Haas, *Partner, Latham and Watkins, LLP*
 - Sabine Haubenreisser, *European Medicines Agency, Liaison Official to U.S. Food and Drug Administration*
-

THURSDAY, JULY 17, 2014: TRADE AND INVESTMENT LIMITS ON REGULATORY MEASURES

Day 4 will examine the restraints that international trade and investment agreements impose on domestic regulation of food and drugs. These restraints have been highlighted by recent disputes at the WTO and international arbitration fora.

9:30 AM-11:00 AM

TRADE, INVESTMENT AND FOOD AND DRUG REGULATORY MEASURES: BASIC PRINCIPLES OF TRADE POLICY AND LAW

This session will examine:

- The impacts of trade and investment policies on planning and implementing regulatory measures including ractopamine content limitations and genetically modified organism labeling rules
- The law and structure of the WTO with special emphasis on the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade
- Principles of non-discrimination and necessity and how they have been invoked in disputes concerning food and drug regulatory measures.

SPEAKER

Benn McGrady, *Project Director, Trade, Investment and Health Initiative, O'Neill Institute; Adjunct Professor, Georgetown University Law Center*

11:00 AM-11:15 AM

COFFEE BREAK

11:30 AM-12:45 PM

REGULATORY HARMONIZATION, COOPERATION, AND MEMORANDA OF UNDERSTANDING

The session will analyze:

- FDA's current mutual recognition policies and memoranda of understanding with foreign national regulatory authorities
- Regulatory harmonization efforts under way in member countries of the African Union
- Regulatory harmonization efforts under way in the region of the Americas

SPEAKERS

- Michele Forzley, *Senior Scholar and Careers and Externships Advisor, O'Neill Institute*
- Katherine Cooper, *Senior Policy and Strategy Analyst, Office of Strategy, Partnerships, and Analytics, Office of International Programs, U.S. Food and Drug Administration*
- José Luis Castro, *Advisor, Rationale Use of Medicines, Pan American Health Organization*

12:45 PM-2:00 PM

LUNCH

2:00 PM-3:45 PM

THE CODEX ALIMENTARIUS AND THE FOOD SAFETY MODERNIZATION ACT

This session will examine:

- Codex Alimentarius Commission Decision-Making with emphasis on Guidelines on Nutrition Labeling, Guidelines for Use of Nutrition and Health Claims and the General Standard for the Labeling of Prepackaged Foods
- Consumer Protection and enforcement aspects of the Food Safety Modernization Act
- The general regime of food import regulation in the US and the operationalization of new regulations under the Food Safety Modernization Act

SPEAKERS

- Chris Waldrop, *Director, Food Policy Institute, Consumer Federation of America*
- Sharon Mayl, *Senior Advisor for Policy, US Food and Drug Law Administration*
- Aliza Glasner, *Institute Associate, O'Neill Institute*
- Moderator: Sam Halabi, *Scholar, O'Neill Institute*

3:45 PM-4:00 PM

BREAK

4:00 PM-5:30 PM

FOOD AND DRUG REGULATION IN INDIA: PRIORITIES FOR THE NEW GOVERNMENT

This lecture will focus on:

- The profile of Prime Minister Modi's new government
- Clinical trials litigation
- India's prescription drug market and Schedule H
- Doing business in India after the election: continuity and change

SPEAKER

- Vince Suneja, *Chief Executive Officer, TwoFour Insight Group, LLC; former First Secretary, Market Access & Compliance Attaché at the US Embassy in New Delhi, India*
-

FRIDAY, JULY 18, 2014: NATIONAL AND INTERNATIONAL FOOD AND DRUG REGULATION: THE OPEN QUESTIONS

The final day of the summer program will focus on two substantial sources of uncertainty in the future of food and drug regulation: regulatory capacity in low and middle-income countries (LMICs) and the Affordable Care Act

9:30 AM-11:00 AM

NECESSARY INVESTMENTS IN REGULATORY INFRASTRUCTURE AND WORKING WITH GOVERNMENTS LACKING REGULATORY CAPACITY

This session will focus on the key regulatory failures in low and middle income countries and best practices for working with LMICs while avoiding the appearance of corruption, including:

- Pfizer Pharmaceutical's compliance plan for working LMICs while complying with the US Foreign Corrupt Practices Act
- Priority areas for investment in regulatory infrastructure

SPEAKERS

- John Monahan, *Senior Advisor to the President for Global Health and Senior Fellow, McCourt School of Public Policy, Georgetown University; Former Counselor to the Secretary and Director, Office of Global Health Affairs, US Department of Health and Human Services (HHS)*
- Parth Chanda, *Senior Corporate Counsel, Compliance, Pfizer Pharmaceuticals*
- Bruce Gellin, *Deputy Assistant Secretary for Health; Director, National Vaccine Program Office, US Department of Health and Human Services (HHS)*
- Moderator: Sam Halabi, *Scholar, O'Neill Institute*

11:00 AM-11:15 AM

COFFEE BREAK

11:15 AM-12:45 PM

THE AFFORDABLE CARE ACT AND CONGRESSIONAL PRIORITIES FOR FOOD AND DRUG REGULATION

This panel will examine uncertainties arising under the major health reform legislation in the US as well as forecast Congressional priorities in the wake of the Food Safety Modernization Act and the Food and Drug Safety Administration Innovation Act, including:

- How the essential benefit package will share pharmaceutical demand in the near and long term
- Nutritional labeling aspects of the Affordable Care Act and likely challenges and changes in food advertising and labeling
- An interactive discussion of the issues

SPEAKERS

- Timothy Westmoreland, *Professor of Practice, O'Neill Institute; Former Counsel to the Subcommittee on Health and the Environment, US House of Representatives*
 - Samuel R. Wiseman, *Assistant Professor, Florida State University*
-

12:45 PM-2:00 PM

LUNCHTIME TALK AND OPEN FORUM FOR UNANSWERED QUESTIONS

This interactive session will provide a forum for:

- Participants to ask any unanswered questions
- Discussion of the issues directed by participants

2:00 PM-2:15 PM

GROUP PHOTO
(OUTSIDE IN COURTYARD AREA)
