AGENDA — current as of 4/10/12

Tuesday, April 24

7:00 – 8:15 a.m.
Registration and Continental Breakfast

8:15 – 8:30 a.m.
Opening Remarks
Susan C. Winckler, RPh, Esq, President & CEO, FDLI
Geoffrey M. Levitt, Senior VP & Associate General Counsel, Regulatory & Policy, Pfizer, Inc. and Chair, FDLI

8:30 – 9:00 a.m.
Keynote Address
Margaret A. Hamburg, MD, Commissioner of Food and Drugs
Introduced by Geoffrey M. Levitt, Senior VP & Associate General Counsel, Regulatory & Policy, Pfizer, Inc. and Chair, FDLI

9:00 – 10:00 a.m.
FDA Deputy Commissioners Roundtable

As part of an effort to more accurately reflect the agency’s responsibilities, subject matter expertise and mandates in an ever more complex world, FDA Commissioner Hamburg re-organized the Agency in mid-2011. The Commissioner divided the Agency’s programs into four directorates that reflect the core functions and responsibilities of the Agency. Hear three Deputy Commissioners introduce their Directorates and discuss the challenges and opportunities they expect to address in the next year.

Deborah M. Autor, Deputy Commissioner for Global Regulatory Operations and Policy, FDA
Stephen P. Spielberg, MD, Deputy Commissioner for Medical Products and Tobacco, FDA
Michael R. Taylor, Deputy Commissioner for Foods, FDA
Moderated by Susan C. Winckler, RPh, Esq

10:00 – 10:30 a.m.
Networking Break

10:30 – 11:50 a.m
Regulatory Science:
Redefining FDA in 2012

Since FDA launched its Strategic Plan for Regulatory Science in October 2010, stakeholders ranging from pharmaceutical companies to patient advocates to universities and venture capitalists have been working with FDA to successfully utilize the new program. But what, exactly, is the definition of regulatory science? And what has the new initiative accomplished? In this roundtable, you’ll hear differing perspectives on this important development, including:

• The impact of the new tools, standards, and approaches established to assess the safety, efficacy, quality, and performance of all FDA-regulated products;
• FDA “building arrangements” and what they mean;
• Avoiding perceived conflicts of interest;
• Challenges ahead and improvements that can be made to the regulatory science initiatives; and,
• Cooperative relationships between industry and FDA to promote regulatory science.

Vicki Seyfert-Margolis, PhD, Director, Office of Science and Innovation, Office of the Chief Scientist, OC, FDA
Kenneth L. Dretchen, PhD, Director of the Georgetown University Biosecurity Institute
William McConagha, Fellow, Majority Staff, Senate Committee on Health, Education, Labor, and Pensions
Lance L. Shea, Partner, Fulbright & Jaworski L.L.P.
Moderated by Geoffrey M. Levitt, Senior VP & Associate General Counsel, Regulatory & Policy, Pfizer, Inc. and Chair, FDLI
11:50 a.m. – 12:10 p.m.
**FDA Alumni Association Award Presentation**

A lectureship named in honor of Dr. Harvey W. Wiley, the renowned physician-chemist who, at the turn of the 20th century, championed a legislative crusade against food adulteration, earning him the title of “Father of the Pure Food and Drugs Act” when it was enacted into law in 1906.

The 2012 Wiley Award Winner is Steve Usdin. Mr. Usdin has been Washington Editor of BioCentury since 1993, and has spent the past 20 years in Washington, DC covering political and policy issues affecting the life sciences sector. He also is the Senior Editor responsible for coverage of social issues involving biotechnology. His book, “Engineering Communism: How Two Americans Spied for Stalin and Founded the Soviet Silicon Valley,” was published in 2005 by Yale University Press. Mr. Usdin also hosts a TV show, “BioCentury This Week,” designed to help the public and policy makers “understand how politics, regulatory decisions, investor attitudes, bioethics and global competition will determine whether biotechnology fulfills its social promise.” His show, the first of its kind to be broadcast on a network TV station and webcast around the world -- has featured interviews with FDA leaders on cutting edge regulatory and public health issues.

12:10 – 1:30 p.m.
**Lunch Address:**
FDA & Global Regulation

Dara Corrigan, Associate Commissioner, Office of Regulatory Affairs, FDA
Daniel Shaw, Vice President and Deputy General Counsel, H.J. Heinz Company

*Moderated by* Luciano Ferreira, Regulatory Intelligence Manager, Latin America, GE Healthcare & Coordinator Professor, Pontifical Catholic University of São Paulo

1:30 – 3:00 p.m.
**Concurrent Breakouts**

FDA Product Center Directors

Representatives from each of FDA’s six product Centers will discuss the three most important developments from the last year and their three most important goals in 2012. You’ll hear directly from Center representatives, as well as food and drug law stakeholders responding to their presentations.

**CTP**

Lawrence Deyton, MSPH, MD, Director, Center for Tobacco Products, FDA
James E. Dillard III., Senior Vice President, Altria Client Services, Inc.

Nancyellen Keane, Of Counsel, Troutman Sanders LLP
Matthew L. Myers, President, Campaign for Tobacco Free Kids

*Moderated by* Mark Frankel, Director, Program on Scientific Responsibility, Human Rights and Law, AAAS

**CVM**

Bernadette M. Dunham, DVM, PhD, Director, Center for Veterinary Medicine
Edward J. Allera, Co-managing Shareholder, FDA/Biotech Chair, Buchanan Ingersoll & Rooney PC
R. Michael Herrman, Senior Division Counsel, Boehringer Ingelheim Vetmedica, Inc.
Roseann Termini, MEd, Professor, Widener University School of Law

*Moderated by* Jeannie M. Perron, DVM, Of Counsel, Covington & Burling LLP

**CFSAN**

Daniel L. Engeljohn, PhD, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, USDA
Michael M. Landa, Director, Center for Food Safety and Applied Nutrition
Ann M. Boeckman, Chief Counsel, Food Law, Kraft Foods Global
Tony Corbo, Senior Lobbyist, Food & Water Watch
Frederick H. Degnan, Partner, King & Spalding

*Moderated by* Leslie Krasny, Partner, Keller and Heckman LLP

**CDRH**

William Maisel, MD, MPH, Deputy Director for Science, Office of the Center Director, Center for Devices and Radiologic Health (as designated by Jeffrey Shuren, MD, Director, Center for Devices and Radiological Health)
Jeffrey K. Shapiro, Director, Hyman, Phelps, & McNamara P.C.
Patricia B. Shrader, Senior Vice President, Corporate Regulatory, and External Affairs, Medtronic, Inc.
Timothy Wells, President, QualityHub,Inc
Diana Zuckerman, Ph.D., President, National Research Center for Women & Families, Cancer Prevention and Treatment Fund

*Moderated by* Daniel A. Kracov, Partner, Arnold & Porter LLP

**CBER**

Mary Malarkey, Director, Office of Compliance and Biologics Quality
Diane M. Maloney, Associate Director for Policy, CBER, FDA
Kay Holcombe, Senior Policy Advisor, Genzyme
Celia M. Witten, PhD, MD, Director, Office of Cellular, Tissue and Gene Therapies
Stephen Paul Mahinka, Partner, Morgan, Lewis & Bockius LLP

Moderated by Jordan Paradise, Associate Professor of Law, Seton Hall University School of Law

CDER
Douglas Throckmorton, MD, Deputy Center Director, Center for Drug Evaluation and Research (as designated by Janet Woodcock, MD, Director, Center for Drug Evaluation and Research)
Jonca Bull, MD, Novartis Pharmaceuticals Corporation
David M. Fox, Partner, Hogan Lovells
Robert Rhoades, Vice President, Quality & Compliance Consulting, Quintiles
Moderated by Michelle R. Mangrum, Managing Partner, Shook, Hardy & Bacon L.L.P

3:00 – 3:30 p.m.
Networking Break

3:30 – 5:00 p.m.
Concurrent Breakouts:

Global Issues

Medical Products
What Every Medical Products Stakeholder Needs to Know about What’s Happening in China

For years, China has led the world’s emerging economies in both the global pharmaceutical and medical device businesses. Keeping current with regulation and business practices is essential for anyone interested in the Chinese market. In this session, experts in the Chinese pharmaceutical and medical device industries and foreign investment in the region will discuss what you need to know to successfully play in this space. This session will include discussion of:

• How product localization is changing the game;
• How newly issued Chinese GMPs affect the supply chain;
• Why developments in the Chinese regulatory regime are significantly affecting the life science industry in China; and,
• What price controls by National Development and Reform Commission (NDRC) of the People’s Republic of China mean for stakeholders.

Katherine Lu, Managing Director, China Healthcare Equity Research, Cowen and Company
Paul Neureiter, Senior Director for International Trade, Pfizer
Chen Yang, Partner, Sidley Austin LLP
Moderated by Josh Berlin, Executive Editor & Director of Business Development, Elsevier Business Intelligence

Medical Products
Why Do FDA-Regulated Medical Product Companies Report Going Abroad to Develop New Products?
Medical device and pharmaceutical manufacturers, government regulators, and other stakeholders are concerned about the growing trend of product development overseas. What factors in the U.S. regulatory approval process affect business development decisions? Explore how the medical product industry is increasingly:

• Weighing the benefits of increased regulatory scrutiny and potential cost to competitive edge and innovation;
• Assessing the effect on patients of the decision to go abroad to pursue approval of the newest medical technologies and treatments; and
• Exploring ways to make the FDA approval process more predictable and consistent.

Sheila Hemeon-Heyer, RAC, President, Heyer Regulatory Solutions, LLC
Christopher-Paul Milne, Assistant Director of the Tufts Center for the Study of Drug Development, Tufts University
Gael Tisack, Vice President of Regulatory and Legal Affairs, Terumo Cardiovascular Systems
Andrew Van Haute, Associate General Counsel, AdvaMed
Moderated by Jennifer Bragg, Partner, Skadden, Arps, Slate, Meagher & Flom LLP

Dietary Supplements/Cosmetics
Emerging Markets for Dietary Supplements and Cosmetics: Key Compliance, Safety and Regulatory Issues

Dietary supplement and cosmetic manufacturers are increasingly seizing opportunities to produce and distribute product to emerging markets, especially China, India and Brazil. But, with opportunity comes a raft of challenges, including GMP standards, supply chain integrity, import requirements and compliance with myriad regulatory schemes. In this session, you’ll find out:

• Where cosmetics and dietary supplement manufacturers are investing their resources internationally and the legal and regulatory obstacles they face;
• What supply chain and safety issues are integral to regulatory compliance globally; and
• The latest trends in international regulation of dietary supplements and cosmetics as food and/or drugs.

Daniel Fabricant, PhD, Director, Division of Dietary Supplement Programs, FDA
Rend Al-Mondhiry, Regulatory Counsel, Council for Responsible Nutrition
Francine Lamoriello, Executive Vice President, Global Strategies, Personal Care Products Council
Georgia Ravitz, Partner, Arent Fox LLC
Moderated by Mark Mansour, Partner, Akin Gump Strauss Hauer & Feld LLP

Food
How FSMA Changed the Game on Imports
Under the Food Safety Modernization Act (FSMA), FDA's new import authority and mandates include importer accountability, third-party accreditation, certification of high risk foods, voluntary qualifier importer programs and authority to deny entry into the country. Operating in a global market requires food manufacturers and processors to understand the evolving import and accreditation requirements to remain competitive at home and abroad.
In this session you will learn:
• How to develop and implement compliant accreditation, certification and supplier verification programs;
• How FDA is likely to implement new food security measures;
• How consumers can be adequately protected under FSMA mandates;
• How FSMA will affect multilateral trade and supply chain integrity issues; and
• How to develop and implement a foreign supplier verification program that is right for your business.

Benjamin England, President and CEO, FDAImports.com, LLC
Bruce Silverglade, Principal, Olsson, Frank, Weeda, Terman, Bode, Matz, P.C.
Christopher A. Waldrop, Director, Food Policy Institute, Consumer Federation of America
Moderated by Sarah Roller, Partner, Kelley Drye & Warren LLP

Veterinary Medicine/Animal Drugs
Antibiotic Use: Feed Animals and Antibiotic Resistance: A Global Challenge

Antibiotic resistance is a growing global problem. In January 2012, FDA partially banned certain extra-label uses of cephalosporin, a class of antimicrobial drugs and a critical component of human medicine in certain food-producing animals. The action was applauded by some and challenged as insufficient by others. As the world's food supply and trade of animal feed becomes increasingly globalized and antibiotic resistance permeates, what steps are the U.S., the European Union and other governing bodies taking?
In this session, leaders in the field will:
• Analyze FDA's regulation of animal drugs and collaboration with foreign regulatory agencies,
• Explore the international patterns of resistance and efforts to address the problem and
• Examine resistance analysis, resistance development to antibiotics in the meat industry.

Carlos Alvarez Antolinez, DVM, Minister Counselor, Food Safety, Health and Consumer Affairs, Delegation of the European Union
Betsy Booren, PhD, Director, Scientific Affairs, American Meat Institute
H. Scott Hurd, Associate Professor, Director, WHO Collaborating Center for Risk Assessment and Hazard Identification, Iowa State University
Jesse J. Sevcik, Director, Global Government Affairs, Elanco Animal Health, Eli Lilly & Company
Moderated by Suzanne O'Shea, Counsel, Faegre Baker Daniels LLP

Tobacco
Tobacco Research in a Post-Statute World
This panel will engage experts on critical issues resulting from tobacco research being conducted after passage of the Tobacco Prevention and Control Act. These issues involve key regulatory and policy issues, including the pathways for different tobacco products and the continuing development of FDA's role. In this session, the panel will consider:
• Concerns regarding industry funding of required research;
• Long-term options for a tobacco research infrastructure, including models such as the Health Effects Institute and the Hamner Institutes for Health Sciences;
• Research required for a modified risk tobacco product application, including the level of tobacco company oversight provided for industry-funded studies;
• FDA collaboration with external research entities, including those prescribed by the Institute of Medicine; and
What companies can do on their now, including forming a company-sponsored oversight/advisory body and ensuring independence and credibility.

J. Ben Haas, Partner, Latham & Watkins LLP
Lars-Erik Rutqvist, MD, PhD, Senior Vice President Scientific Affairs, Swedish Match AB
Kathleen Stratton, Project Director, Innovate FDA, Pew Health Group

Moderated by Jim Solyst, Principal Consultant, ENVIRON

Networking Reception

Wednesday, April 25

7:00 – 8:30 a.m.
Registration and Continental Breakfast

8:30 – 10:00 a.m.
Top 20 Cases in Food and Drug Law in 2011

Drawing from FDLI's 2012 edition of Top 20 Cases, food and drug law professors will discuss the legal and practical impact—on the entire food and drug law community—of four of 2011’s most wide-sweeping cases and highlight cases to watch in 2012:

J. McIntyre Machinery, Ltd. v Nicastro (jurisdiction issues in products liability action)
R.J. Reynolds Tobacco Co. v. United States Food and Drug Administration (a constitutional challenge to required graphic warning labels on cigarette packaging)
United States v. Caronia (pharmaceutical sales representative prosecuted for off-label promotion)
Prometheus v. Mayo (whether method tests are patentable)

Jonas Anderson, Assistant Professor of Law, American University
Lewis A. Grossman, Professor of Law, American University
William Janssen, Associate Professor of Law, Charleston School of Law
Allison Zieve, Director, Public Citizen Litigation Group

Moderated by John Reiss, Partner, Saul Ewing LL

10:00 – 10:30 a.m.
Networking Break

10:30 – 12:00 p.m.
Concurrent Breakouts: Emerging Issues

Drugs/Biologics
How Congress and Patient Advocacy Groups Are Changing the Drug Development and Approval Paradigm

For many years, Congress and patient advocacy groups have attempted to expedite or change the current drug development and approval regulatory scheme. The Spending Reductions through Innovations in Therapies legislation, pending in the 112th Congress, is aimed at spurring innovation in research and drug development for chronic health conditions, such as Alzheimer’s. Patient advocacy group interventions have varied from advocacy campaigns to direct research funding. In this session, you’ll hear leaders in field discuss:

• Different approaches used by advocacy groups to promote drug innovation;
• Recent efforts by Congress to pass legislation that would spur development of potential therapies for chronic diseases;
• Federal Government and other efforts to find more effective therapies for treating Alzheimer’s.

Diane Dorman, Vice President of Public Policy, National Organization for Rare Disorders
Mary Booth Dwight, Vice President, Government Affairs, Cystic Fibrosis Foundation
James O’Leary, Chief Innovation Officer, Genetic Alliance

Moderated by Margaret A. Anderson, Executive Director, Faster Cures

Drugs/Medical Devices
Social Media & New Technology: FDA Guidance, Mobile Apps & Digitization

Social media and new technology are directly affecting the FDA regulatory environment. Increasingly, the agency itself is using social media to disseminate important information. At the same time, the medical products industry is seeking further FDA guidance on industry use of this growing phenomenon. Social media is also part of a paradigm shift in technology that is disrupting the medical products community, including the digitization of promotional literature and the proliferation of mobile applications. In this session, experts will discuss:

• What Does/Would FDA Guidance on Social Media Really Mean?
• How Will FDA Regulate Mobile Devices and What Does the Adverse Events App RFP Mean for Stakeholders?
• Why is Digitization So Crucial to Medical Products?

Dale Cooke, Vice President/Group Director, Regulatory, Digitas Health
Alan S. Goldberg, Attorney and Counsellor-at-Law, and Adjunct Professor, Health Law, George Mason School of Law
Sara Stults, Vice President and Senior Consultant, Searchlight Compliance Advisors

Moderated by Bradley Merrill Thompson, Partner, Epstein Becker & Green, P.C.

Food/Dietary Supplements
Functional Foods: How Foods, Dietary Supplements and Pharmaceuticals Are Becoming Increasingly Intertwined

“Functional foods” continue to be a rapidly growing area of the consumer food market. With increased scrutiny from regulatory bodies and private litigation, keeping informed on the complex relationship between food, dietary supplements and drugs is more important than ever. With no formal definition of “functional foods” and an increased demand from health-conscious consumers, the potential for innovation and development that make functional foods an emerging field in food science is immense. In this session, stakeholders will learn about the complex issues proliferating the production, marketing and development of functional foods and ingredients, including:

• What is a functional food?
• How to define identity and functionality attributes of novel ingredients;
• How to navigate health claims and what type of substantiation is required; and
• Where is the line drawn between food, dietary supplements and drugs?

Todd Harrison, Partner, Venable LLP
Joshua S. Kim, Food Law Lawyer, Cargill, Inc.
Markus Lipp, Director Food Standards, United States Pharmacopeia

Moderated by Stuart M. Pape, Partner, Patton Boggs LLP

Medical Products and Tobacco
MRTPs and Nicotine: Building a Comprehensive Policy

This panel will review the current state of modified risk tobacco products (MRTPs) regulation, building from the December 2011 Institute of Medicine (IOM) report on the scientific standards for study of MRTPs. Panelists will explore the challenges facing industry and FDA in addressing the full spectrum of nicotine delivery products and replacement products from Rx drugs to OTC products to tobacco. Specific topics include:

• The continuum of risk and the practical impact of FDCA's Section 911 mandate that FDA make decisions based on individual risk reduction and public health benefit:
• A case study of the UK’s explicit indication for harm reduction for Nicotine Replacement Therapy (NRT) and consideration of continued smoking as an appropriate comparator when evaluating new NRT products or indications: and
• Implications for tobacco and drug regulatory policy in the U.S.

Carlos Angulo, Partner, Zuckerman Spaeder LLP
Scott Ballin, Health Policy Consultant
James E. Swauger, PhD, DABT, Vice President, RAI Services, Inc.
Mitchell R. Zeller, Senior Vice President, Pinney Associates

Moderated by David Clissold, Director, Hyman, Phelps & McNamara, P.C.

Ethics (CLE)
An Exploration of Ethical Issues Raised by Lauren Stevens, Stryker Biotech and Similar Cases

In May 2011, the government prosecuted a senior pharmaceutical industry attorney for her role in responding to a government information request and the court dismissed the charges against her at the close of the government’s case. In January 2012, the government dismissed all charges against four executives of Stryker Biotech shortly after the case began.

These cases offer several lessons and raise numerous ethical and professional responsibility issues, including:

• What’s the role and responsibility of in-house and outside counsel in responding to government information requests?
• What attorney-client communications can the government gain access to?
• What are the challenges in reconciling an attorney’s duty to the client with their duty to serve the judicial system and adhere to the ethics rules?
• When must a company’s attorney-client privilege yield to an employee’s right to defend himself/herself?

Colleen A. Conry, Partner, Ropes & Gray
Brent Gurney, Partner, WilmerHale
Frederick Ball, Partner, Duane Morris LLP

Moderated by Ralph Hall, Distinguished Professor and Practitioner, University of Minnesota Law School
**Working in the Food and Drug Law Space: Challenges and Opportunities**

The opportunities for employment in the food and drug law, regulation and policy space are virtually boundless. Hear from FDA officials, private sector attorneys, manufacturers and consultants on the challenges and opportunities presented in this burgeoning field.

John M. Taylor III, Counselor to the Commissioner, FDA  
Nancy Myers, President, Catalyst Healthcare Consulting, Inc.  
John Packman, Senior Counsel, Food Law, The Coca-Cola Company  
Marc J. Scheineson, Partner, Alston & Bird LLP  
*Moderated by* Stuart TenHoor, President, TenHoor, Inc.  
Legal Search Services

12:00 – 1:30 p.m.  
**Networking Lunch**

1:30 – 2:00 p.m.  
**Address from the Office of Chief Counsel at FDA**  
Elizabeth H. Dickinson, Chief Counsel, FDA

*Introduced by* Elizabeth H. Anderson, Executive Vice President & General Counsel, Personal Care Products Council and FDLI Board Vice Chair

2:00- 3:15 p.m.  
**Former FDA Chief Counsels Roundtable**

Gather insight from former FDA Chief Counsels on the role of the Chief Counsel, the challenges faced in this role and how the role has evolved.

Sheldon T. Bradshaw, Nancy L. Buc, Richard M. Cooper,  
Peter Barton Hutt, Gerald F. Masoudi, Daniel E. Troy,  
Ralph Tyler  
*Moderated by* Minnie V. Baylor-Henry, Worldwide Vice President for Regulatory Affairs, Medical Devices & Diagnostics, Johnson & Johnson and FDLI Immediate Past Board Chair

3:15 – 3:45 p.m.  
**Networking Break**

3:45 – 5:15 p.m.  
**Innovation in FDA-Regulated Industries — 2012**

They’re not your father’s food and drug-regulated industries any more. In a more complex (and more regulated) world, stakeholders are exploring new ways to develop products, secure FDA approval and proceed to commercialization. In this session, you’ll find out how

Karen M. Becker, PhD, President, IndigoBay Ventures, LLC  
Robin Feldman, Professor of Law, Director, LAB Project, UC Hastings  
Angela Lim, Senior Manager, Regulatory Affairs NAFTA, DuPont Nutrition and Health  
Robert Schwarzberg, MD, President & CEO, Sensei, Inc  
Amit N. Shah, MD, Director, MedStar Inventor Services, MedStar Institute for Innovation, MedStar Health  
Felasfa Wodajo, MD, Senior & mHealth editor, iMedicalApps  
*Moderated by* Greg Szwartz, Director, Applied Analytics Deloitte Consulting LLP