European Certificate in Healthcare Compliance, Ethics & Regulation

presented by

SETON HALL LAW SciencesPo.

Day 1: Monday, Nov. 12, 2012 **Global Anti-Corruption Enforcement Efforts**		
Time	Agenda Item	Speakers
10:00-10:30	***Registration***	
10:30-11:00	Welcome and Introduction	**Marie-Hélène WEBER-GOUBIN** SciencesPo (Paris) **Simone HANDLER-HUTCHINSON** Seton Hall Law School (Newark, NJ)
11:00-12:20	An Introduction to Global Anti-Corruption Issues and Enforcement Efforts	**Sarah GEIGER** TRACE International, Inc.
12:20-13:20	***Lunch***	
13:20-14:20	Lessons Learned from US Healthcare Fraud & Abuse Enforcement & Compliance Programs	**Kathleen BOOZANG** Professor of Law, Seton Hall Law School (Newark, NJ)
14:20-15:35	To Europe & Beyond: The Impact of the US Foreign Corrupt Practices Act • Legal Requirements; Anti-bribery provisions; Books & Records provisions • Cases and enforcement • Third party Due Diligence	**Frederick T. DAVIS** Partner, Debevoise & Plimpton LLP (Paris)
15:35-15:55	***Break***	
15:55-17:00	The UK Bribery Act: How Its Extraterritorial Reach Affects You and Your Business	**Matthew GETZ,** Associate, Debevoise & Plimpton LLP (London)
17:00-18:00	***Interactive Class Discussion:*** Developing culture of ethics and compliance within your organization.	***Discussion Leaders:*** **Roeland VAN AELST** Vice President, EMEA & Canada, Office Health Care Compliance & Privacy, Johnson & Johnson (Brussels) **Kathleen BOOZANG** Professor of Law, Seton Hall Law School (Newark, NJ)

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DAY 2: TUESDAY, NOV. 13, 2012
REGULATORY FRAMEWORK FOR DRUGS & DEVICES

Time	Agenda Item	Speakers
09:00-10:30	Overview of Approval Process for: • New Drugs & Devices • Clinical Trials	**Geneviève MICHAUX** Covington & Burling LLP (Brussels)
10:30-10:50	***Break***	
10:50-12:20	Advertising and Promotion: Drugs, Devices & OTC Products • National Legislation • EU harmonization programs on OTC and devices • Social media	**Annabelle BRUYNDONCKX** Counsel, Baker & McKenzie (Brussels) **Thomas DEVRED** Counsel, Baker & McKenzie (Paris)
12:20-13:20	***Lunch***	
13:20-14:40	Scientific Exchange and Educational Activities	**Jonathan SCHUR** **Anthony PARONNEAU** Dechert LLP (Paris)
14:40-15:00	***Break***	
15:00-16:15	Beyond Sales & Marketing: Interactions with Government Officials Throughout the Product Life-cycle • Site regulators • Tender advisors • Regulatory consultants	**Jean-Claude NAJAR** General Counsel France & Senior Counsel Europe, GE. (Paris)
16:15-17:30	***Interactive Session:*** Compliance Officers Panel Discussion, Q&A	**Dominique LAYMAND** Vice President Compliance & Ethics EMEA, Bristol-Myers Squibb (Paris) **Chris ZALESKY** Vice President, Global Policy & Guidance, Johnson & Johnson (US) **Jean-Claude NAJAR** General Counsel France & Senior Counsel Europe, GE. (Paris) **Gerald ORLIK,** Regional Compliance Officer Europe, Sanofi (Paris) ***Moderator:*** **Kathleen BOOZANG** Professor of Law, Seton Hall University School of Law (NJ)
19:00-21:00	***Welcome Dinner for Program Participants & Faculty***	(tbd) Maison de l'Amérique Latine 217 Bd Saint-Germain F-75007 Paris

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DAY 3: WED., NOV. 14, 2012 **REIMBURSEMENT, INDUSTRY CODES & SELF-REGULATION**		
Time	Agenda Item	Speakers
09:00-10:30	Healthcare Reimbursement & Delivery Programs in Europe • Public, Private, Mixed • Social security systems • Medicines, OTC, Devices	**Marie-Paule SERRE** Professor, Pierre et Marie Curie University of Paris
10:30-10:50	***Break***	
10:50-11:35	EFPIA Codes of Practice • Setting a code • Enforcing a code/vigilance • To what extent do voluntary industry codes have legal ramifications • New initiatives & updates	**Marie-Claire PICKAERT** Deputy Director General, EFPIA
11:35-12:20	EUCOMED Codes & Guidelines on Interactions with HCPs • Setting & enforcing a code • To what extent do voluntary industry codes have legal ramifications • New initiatives & updates	**Aline LAUTENBERG** Legal Counsel, Eucomed (Brussels)
12:20-13:20	***Lunch***	
13:20-15:00	Industry Self-Regulation • The View from Spain • The Role of Eucomed's Compliance Panel	**José ZAMARRIEGO IZQUIERDO** Director Unidad de Supervisión Deontológica, FARMAINDUSTRIA (Madrid) **John MCLOUGHLIN** Member, Eucomed Compliance Panel
15:00-15:20	***Break***	
15:20-16:20	Global Transparency Trends: US, UK, France, Europe & Beyond • Laws & pending legislation • Voluntary industry codes	**Suzanne RAB** Partner, King & Spalding (London)
16:20-17:30	***Roundtable Discussion:*** The challenges of implementing industry codes of ethics and transparency requirements.	***Invited:*** **John MCLOUGHLIN, José ZAMARRIEGO IZQUIERDO, and Aline LAUTENBERG, Suzanne RAB** ***Moderator:*** **Kathleen BOOZANG**

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DAY 4: THURSDAY, NOV. 15, 2012 COMPETITION, PRIVACY & PROCUREMENT LAW		
Time	Agenda Item	Speakers
9:00-10:15	EU Competition Law in Healthcare	**Edward MILLER** Partner, Reed Smith (London)
10:15-11:15	EU Competition Law Enforcement: Overview of Authority, Powers & Practical Tips	**Kurt HAEGEMAN** Partner, Baker & McKenzie (Brussels)
11:15-11:35	***Break***	
11:35-12:45	Privacy Laws as Related to Anti-corruption Compliance	**Kristof VAN QUATHEM** Data Protection Advisor, Covington & Burling LLP (London)
12:45-13:45	***Lunch***	
13:45-15:15	Anatomy of FCPA Investigations • Current enforcement landscape • How an investigation begins • Dealing with internal investigations • Responding to government inquiry • Special areas of interest	**Kirk OGROSKY** Partner, Arnold & Porter LLP (DC), former Deputy Chief for Health Care Fraud, Criminal Div., U.S. Department of Justice **Chris ZALESKY** Vice President, Global Policy & Guidance, Johnson & Johnson (US)
15:15-15:35	***Break***	
15:35-17:00	***Teamwork:*** Meet with team members to review, analyze and prepare for case studies session.	Assigned teams

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DAY 5: FRIDAY, NOV. 16, 2012 **COMPLIANCE EFFECTIVENESS AND CASE STUDIES**		
Time	Agenda Item	Speakers
9:00-10:20	Assessing and Demonstrating Compliance Program Effectiveness • Activity measures • Outcomes measures	**Ian BEALE** Senior Director for our European Corporate Integrity Practice, Compliance and Ethics Leadership Council (CELC)
10:20-13:00	***Interactive Session:*** Group Case Studies Workshop 10:15: Team instructions 10:30-11:45: Teams to evaluate proposed activities, assess risk, and provide recommendations. 11:45-13:00: Classroom discussion	***Discussion Leaders:*** **Dominique LAYMAND** Vice President Compliance & Ethics EMEA, Bristol-Myers Squibb (Paris) **Robert SKINNER** Deputy Compliance Officer, Emerging Markets, Asia Pacific & Japan, GlaxoSmithKline
13:00-14:00	***Closing Luncheon, Remarks and Awarding of Program Certificates***	**Marie-Hélène WEBER-GOUBIN** SciencesPo **Simone HANDLER-HUTCHINSON** Seton Hall Law School

- Conclusion of Program -

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