CURRENT TOPICS
IN LIFE SCIENCES LAW,
REGULATION AND BUSINESS
DEVELOPMENT

June 12, 2014

VILLANOVA UNIVERSITY
SCHOOL OF LAW
299 N. Spring Mill Rd
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CURRENT TOPICS IN LIFE SCIENCES LAW, REGULATION AND BUSINESS DEVELOPMENT

Thomson Reuters and Villanova University School of Law proudly present a special one-day forum on Current Topics in Life Sciences Law, Regulation and Business Development on June 12, 2014.

Helmed by a faculty of industry leaders, this conference will create a formal venue for legal, compliance and business development professionals to discuss impactful topics affecting the Life Sciences sector in 2014 and beyond.

ATTENDEES WILL PARTICIPATE IN BOTH GENERAL SESSION PLENARIES AND SMALLER BREAKOUT DISCUSSIONS ON SUCH TOPICS AS:

- Opportunities Created by the Patient Protection and Affordable Care Act
- Compliance Concerns, Including Anticorruption, Antitrust, Data Privacy and Cybersecurity
- New Strategies for Drug Development and Partnering
- Current Risk Management Issues, Including Clinical Trials and Off-Label Promotion

Intended to showcase the vibrant Life Sciences sector of the greater Philadelphia/New Jersey region, this industry-focused summit offers ample networking opportunities for business and legal professionals to engage, communicate and connect.

TOP REASONS TO ATTEND:

- Learn from the experts: Attend this event and hear compelling discussions from senior lawyers and executives from some of the world’s leading pharmaceutical companies and law firms.
- Network with the vibrant Life Sciences professional community of the greater Philadelphia/New Jersey region, including regulatory experts, industry advisers, top-shelf deal makers and more.
- Stay ahead of the competition with strategic insights from business development thought leaders with deep knowledge of the Life Sciences market.
- For legal professionals, get CLE Credit for in-depth presentations.

WHO SHOULD ATTEND:

- Business development executives
- Legal, regulatory and compliance counsel
- Law firm personnel serving the Life Sciences industry
- Academics focused on the legal issues affecting healthcare

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Goodwin Procter LLP is a leading Global 100 law firm, with offices in Boston, Hong Kong, London, Los Angeles, New York, San Francisco, Silicon Valley and Washington, D.C. The firm’s Life Sciences practice, named the 2014 Biotech Law Firm of the Year by U.S. News-Best Lawyers, provides dedicated, industry-focused representation, with expertise in corporate law, FDA counseling, strategic alliances and intellectual property law, to life sciences companies of all stages, from start-up through mature public company. www.goodwinprocter.com.

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Opportunities from expanded base of
Different avenues for accelerated
Drug discovery on the shelf – repurposing
New provider incentives and penalties
Antitrust and competition developments
New technologies and services that may
Private and public financing for new
Breakthrough designation
Related healthcare IT opportunities
Implementing legislation for
Anticorruption and anti-kickback
Opportunities related to patient-centered
Off-label promotion under the Food,
*PROGRAM AGENDA*
Herman Sanchez & Reath LLP
George H. Kendall Sciences
Gary Keilty Sciences, Point-of-Care Partners
Brian Bamberger Panelists

Health Care and Life Sciences Practice,
George B. Breen Moderator:

• What opportunities exist for business/product
in the US healthcare system in 2014 and beyond?
other participants, such as providers and payors,
field of the PPACA, the US healthcare system
and other participants, such as providers and payors,
in the US healthcare system in 2014 and beyond?
- What opportunities exist for business/product
development as a result?
Additional topics may include:
- Opportunities from expanded base of insured
- New technologies and services that may capitalize on pay-for-performance
- New provider incentives and penalties related to improving quality in a cost effective manner (e.g. services to help avoid readmission or hospital acquired infections that result in penalties)
- Opportunities related to patient-centered outcomes research
- Related healthcare IT opportunities

Moderator:
George B. Breen, Member; Chair, National Health Care and Life Sciences Practice, Epstein Becker & Green, P.C
Panelists:
Brian Bamberger, Practice Lead, Life Sciences, Point-of-Care Partners
Gary Keilty, Managing Director, Huron Life Sciences
George H. Kendall, Partner; Vice Chair, Health Care Practice Group, Drinker Biddle & Reath LLP
Herman Sanchez, Partner, Trinity Partners, LLC

8:45AM Registration & Continental Breakfast
10:45AM Break
9:25AM Opening Remarks
Lisa Passante, Vice President & Associate General Counsel – IP & Science, Thomson Reuters
11:00AM Breakout Discussions
(Choose your track as two concurrent sessions offer conference delegates an opportunity for focused, highly interactive discussions on business development in the life sciences industry and corporate compliance regulation.)
Deal Structures, Execution, Product Purchases & Financing
This workshop will help participants understand the latest trends in successful deal structures, execution, and integration. Our distinguished faculty will offer step-by-step advice on every aspect of the deal process, from letter of intent to integration. Attendees are encouraged to bring their questions and issues.
- Deal structures to secure product pipeline
- Private and public financing for new product development
Moderator:
Spencer D. Klein, Partner, Morrison & Foerster LLP
Panelists:
Rachael Bushey, Vice President, Deputy General Counsel & Corporate Secretary, West Pharmaceutical Services, Inc.
Danielle M. Lauzon, Partner, Goodwin Procter LLP
Cornelius "Neal" P. McCarthy, Managing Director, Fairmount Partners
Brian P. McVeigh, Vice President, Worldwide Business Development Transactions and Investment Management, GlaxoSmithKline plc
Mary Thistle, Senior Vice President, Business Development, Cubist Pharmaceuticals, Inc.

Roundtable on Compliance Concerns at Home and Abroad
This roundtable will discuss the decade-long trend of the regulation of healthcare companies, such as pharmaceutical and biotech companies, through government investigations and settlements. Our distinguished faculty will offer their unique perspectives on current trends in compliance within the healthcare industry, and offer cogent insight into several hot topics, including:
- Anticorruption and anti-kickback compliance
- Off-label promotion under the Food, Drug & Cosmetic Act
- Antitrust and competition developments
- Data protection, privacy and security
Moderator:
John C. Dodds, Partner, Morgan, Lewis & Bockius LLP
Panelists:
Jeffrey Fleming, Vice President Compliance North America, AstraZeneca Pharmaceuticals LP
Jon Smollen, Executive Vice President and Chief Compliance Officer, Endo Pharmaceuticals
Caroline H. West, Senior Vice President, Chief Compliance and Risk Officer, Shire Pharmaceuticals, Inc.
Martin Wilson, Chief Compliance Officer, Vice President – Corporate & Legal Affairs, Par Pharmaceutical Companies, Inc.
12:15PM Luncheon
1:30PM New Strategies for Drug Development
- Drug discovery on the shelf – repurposing and rescuing known candidates
- Latest trends in R&D partnership and platform deals
- Different avenues for accelerated approval
  - Implementing legislation for accelerated approval under FDASIA
  - Breakthrough designation
Moderator:
Anup Kharode, Director, Pharmaceutical & Life Sciences R&D Advisory Services, PricewaterhouseCoopers LLP
Panelists:
John Apathy, Vice President, Research & Development Informatics, Celgene
Bryant Lim, Associate General Counsel, ViroPharma Incorporated
Dr. Barbara E. Tardiff, Vice President, Development Operations; Global Head Clinical Innovation and Informatics, Worldwide Research & Development, Pfizer, Inc.

2:45PM Break
3:00PM Breakout Discussions
(Choose your track as two concurrent sessions offer conference delegates an opportunity for focused, highly interactive discussions on business development in the life sciences industry and corporate compliance regulation.)
PROGRAM AGENDA

**COMPETITION, COLLABORATION & COST FOR LIFE SCIENCE COMPANIES**
- When does intercompany collaboration make sense?
- Precompetitive research collaboration
- Open source opportunities
- Consortia and antitrust issues

**MODERATOR:**
James F. Farrington, Jr., Partner, Chair, Biotechnology & Life Sciences Practice Group, Wiggin and Dana LLP

**PANELISTS:**
Lisa A. DeMarco, Esq., Vice President & Associate General Counsel, Legal Operations – Business Development Transactions, GlaxoSmithKline plc
Beth Hodshon, JD, MPH, RN, Research Manager, Yale Center for Outcomes Research & Evaluation (CORE), Yale University Open Data Access (YODA) Project
Brett Kieger, Chief Commercial Officer, DrugDev
Dr. Marta M. Pineiro-Nunez, Director – Open Innovation Drug Discovery, Eli Lilly & Co.

**CURRENT RISK MANAGEMENT ISSUES IN DUE DILIGENCE**
- Product liability
- Clinical trials
- Legal developments regarding discount safe harbor
- Global regulatory trends in pharmacovigilance

**MODERATOR:**
Alfred J. Monte, Jr., Partner & Chair, Life Sciences Group, Fox Rothschild LLP

**PANELISTS:**
David Dopf, Director and Senior Counsel, Boehringer Ingelheim Pharmaceuticals, Inc.
Jeanine Foran, Chief Compliance Officer, Director, Risk Management, Norwalk Hospital
Elizabeth V. Jobes, Senior Vice President and Chief Compliance Officer, Auxilium Pharmaceuticals
Jason W. Sapsin, MPH, Counsel, Fox Rothschild LLP

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- Brian T. Gorman - Deputy General Counsel, AstraZeneca Pharmaceuticals LP
- Kristin F. Kennedy - Associate General Counsel, Auxilium Pharmaceuticals, Inc.

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