2nd Conference on
Drug and Medical Device Litigation

Managing Liability Through Proactive
Preemption Strategies and
Government Compliance

OCTOBER 24-26, 2007
THE WESTIN NEW YORK AT
TIMES SQUARE, NEW YORK, NY

Gain first-hand knowledge from In-House Counsel, FDA Personnel, Judges, and Industry Experts:

- Hear from the FDA on guidance issues concerning removals and corrections
- Examine the issues behind off-label usage
- Make the best use of Alternative Dispute Resolution
- Evaluate the future of Preemption as a Defense
- Understand the recent trends of both US and international governmental involvement in the drug and medical device industry
- Coordinate competent counsel in drug and device cases
- Install capable defenses and understand how to handle litigation in a crisis
- Hear from experienced Judicial Faculty on MDL and Daubert hearings
- Earn CLE credits while attending (see page 2 for details)

Register & Pay by August 24th & SAVE $800

Hear Case Studies, Opinions, and Presentations by:
- Food and Drug Administration NEW
- Bayer Corporation
- Pfizer NEW
- State Court of Texas, Harris County NEW
- Stratify NEW
- Cubist Pharmaceuticals NEW
- Fulbright & Jaworski LLP NEW
- Surmodics, Inc. NEW
- Aktina NEW
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- Marsh
- Boehringer-Ingelheim NEW
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- US District Court of Minnesota NEW
- Purdue Pharma
- Novartis Corporation NEW
- Finnegan Henderson Farabow Garrett & Dunner LLP NEW
- SSCI Aptuit NEW
- Johnson & Johnson NEW
- Greenberg Traurig LLP (NEW)
- Sidley Austin LLP (NEW)
- Nixon Peabody LLP
- Boston Scientific

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1-800-882-8684 • www.iqpc.com/legaliq
Drug and Medical Device Litigation

Dear Colleague:

Litigation in the pharmaceutical and medical device industry is a fact of life that many companies find difficult to avoid. Consider the facts: testing and approval from the Food & Drug Administration typically takes 7 to 10 years (10 to 15 for compounded drugs), yet the standard patent for a drug or device typically runs only 20 years. Efficiently balancing the best interests of business versus safely exploring innovation, while all the avoiding costly litigation, is a balancing act that continues to confound industry leaders through the present.

The numbers don't lie:

Despite lengthy and thorough test and approval processes at the FDA, the number of industry leaders through the present.

Efficiently balancing the best interests of business versus safely exploring innovation, drugs), yet the standard patent for a drug or device typically runs only 20 years.

Dear Colleague:

Conference Director, Legal IQ,

Blake Morgan

invaluable knowledge on this ever-present issue.

Medical Device Industry. Participate in speaking sessions, interactive workshops, question and answer sessions, panels, and one-on-one meetings to gain

We hope to see you in October!

With kinder regards,

Blake Morgan

Conference Director, Legal IQ, a division of IQPC

Blake.Morgan@iqpc.com

Who will attend:
• General Counsel
• Assistant General Counsel
• Vice Presidents and IP Counsel
• Senior Counsel
• Corporate and Associate Counsel
• Litigation Counsel
• Compliance and Regulatory Directors
• Legal Director
• Corporate and Legal Affairs Manager
• Director of Marketing
• Quality Assurance Managers and Directors
• Patent Counsel

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Source: www.yourlawyer.com/practice_areas/defective_medical_devices

Medical Devices That Have Been Involved in Litigation
• Alaris Infusion Pumps
• Ancure
• Arrow Sheath Introducers
• Baxter Dialysis Filter
• Baxter Infusion Pumps
• Baxter Meridian Hemodialysis
• BioMedical Tissue Services Scandal
• Biomet Hip Replacements
• Bjork-Shiley-Heart Valve
• Boston Scientific Entery Device
• Boston Scientific Express-Stent
• Boston Scientific Flex Spare
• Boston Scientific Infusion Ports
• Boston Scientific Taxus Stent
• Charlie Spinal Discs
• Cochlear Implants
• Composix Kugel Mesh X-Large Patch
• Coredis Precis RX Stent
• Coralix Device
• Disetronic D-tronplus Power Packs
• Disetronic H-Tron Insulin Pump
• Drug Coated Stents
• Genetic Breast Cancer Test
• Guidant Defibrillators
• Guidant Implantable Pacemakers
• Guidant Multi-Link Vision Stent
• Guidant Pacemakers
• Hospital Airway Adapters
• Johnson Johnson Cypher Stent
• LifeCell Untested Tissue Parts
• Lifesite Dialysis
• Lost Mountain Tissue Bank Scandal
• Medisystems Baxter Dialysis
• Medtronic Concerto
• Medtronic Defibrillators
• Medtronic Pacemakers
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• Medtronic Concerto
• Medtronic Defibrillators
• Medtronic Pacemakers
• Minimed Diabetic Insulin Set
• Minstrel Patient Lift
• Olympus Bronchoscope
• Ossinium Knee Implants
• Panacly Sutures
• RTI Body Tissue Parts
• Shirley TracheoSoft
• St Jude Aortic Connector
• St Jude Defibrillators
• Texas Blood Tissue Center Scandal
• Triamcinic Vapour Patch
• Tuogen Medical Tissue Scandal
• Tyco US Surgical Stapler
• Untested Body Parts

Drugs That Have Been Involved in Litigation
• Abilify
• Accutane
• ACE Inhibitors
• Actos
• Actos Adderal
• Advair
• Advil
• Ambien
• Amiodarone
• Aptivus
• Aranesp
• Arava
• Arimidex
• Ascept
• Avandia
• Avonex
• Baycol
• Betaseron
• Bextra
• Blemacine
• Bitter Orange
• Camapath
• Cardizem
• Celebriex
• cella
• Ciprox
• Cloprin
• Clozaril
• Complete MoisturePlus
• Concerta
• Cordarone
• Corex
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• Cymbalta
• Cytotec
• Darvocet
• Darvocet X-Large Patch
• Dioxane
• DuralPad
• DES
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• Diltiazem
• Ditropan
• Doxurubicin
• Durageneic Patch
• Effexor
• Eldel
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• Estradest
• Evista
• Fen-Phen
• Fleet Enema
• Foradil
• Fosamax
• Godoon
• Cipro
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• Betaseron
• Trazodone
• Betaseron
• Biomerics
• Biomet Hip
• Baxter Meridian
• Baxter Infusion Pumps
• Baxter Dialysis Filter
• Baxter Infusion Pumps
• Baxter Meridian Hemodialysis
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• Coredis Precis RX Stent
• Coralix Device
• Disetronic D-tronplus Power Packs
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• St Jude Aortic Connector
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Source: www.yourlawyer.com/practice_areas/defective_medical_devices

www.yourlawyer.com/practice_areas/defective_drugs
Main Conference Day One
Thursday, October 25, 2007

8:00 REGISTRATION AND BREAKFAST
8:30 CHAIRPERSON’S OPENING REMARKS
8:45 UPDATE ON RECENT AND PENDING LITIGATION
    • Detailing recent filings and verdicts in pharmaceutical litigation and examining their implications
    • Highlighting recalls and changes in warnings
    • Investigating the potential for future medical device and drug claims: what are the trends-to-be
    • Examining the positive and negative effects of the institution of private-sector medical coverage versus governmental
    • Updating recent developments of new implementations in Medicaid and examining efficient methods of counterbalancing state and federal demands
    • Investigating drug importation: balancing cost-effectiveness versus compliance with federal regulations

Michael Dore, Partner, Lowenstein Sandler PC
Elpidio Villareal, VP and Associate General Counsel of Litigation and Conflict Management, Schering-Plough

9:30 PROVIDING GUIDANCE TO THE FDA’S STANCE ON REMOVALS AND CORRECTIONS
    • Clearing up confusion with respect to report ability
    • Giving clarity to rule 2 CFR 806.10
    • Discussing the nature of requirements and how enforcement has evolved
    • Determining whether the public good has been well served by the media’s increasingly alarmist approach to device malfunctions

Casper Uldriks, Special Assistant to the Director of Compliance in FDA’s Center for Devices and Radiological Health, FDA

10:15 NETWORKING AND REFRESHMENT BREAK
10:45 EXAMINING THE FUTURE OF PREEMPTION AS A DEFENSE IN DRUG AND DEVICE CASES
    • Determining whether preemption will be a viable defense down the road
    • Examining proposed amendments and provisions in the House Energy & Commerce Health Committee
    • Relating federal preemption to the civil justice system
    • Highlighting how the federal law is trumping state law

Steven Keough, Senior Vice President and General Manager, Orthopedics and Chief IP Counsel, Strympodics, Inc.
Frank Monteleone, General Counsel and VP Pfizer Canada
Joseph Leghorn, Partner, Nixon Peabody LLP

11:30 EXPLORING THE IMPLICATIONS OF CHANGES MADE BY CONGRESS
    • Examining the positive and negative effects of the institution of private-sector medical coverage versus governmental
    • Updating recent developments of new implementations in Medicaid and examining efficient methods of counterbalancing state and federal demands
    • Investigating drug importation: balancing cost-effectiveness versus compliance with federal regulations

George Lykos, General Counsel, Bayer Corporation
I. Scott Bass, Partner & Head of Global Life Sciences, Sidley Austin LLP

12:15 SPEAKER AND DELEGATE LUNCHEON

1:15 EXAMINING THE ISSUES BEHIND OFF-LABEL USAGE
    • Providing guidance and clarity to off-label usage and off-label promotion
    • Exploring and enforcing issues behind off-label usage
    • Recent guidance and compliance on off-label usage
    • Understanding the Food & Monitoring Act

Tanya Berlage, former Chief Counsel of Taro Pharmaceuticals in North America and Partner, Saul Ewing LLP
Paul Weissman, Staff Vice President of Compliance, Schering-Plough
William DeVaul, Senior IP Counsel, Cubist Pharmaceuticals
James M. Becker, Partner and Chair, White Collar and Government Enforcement Practice Group, Saul Ewing LLP

2:00 E-DISCOVERY: CONTROLLING COSTS IN LITIGATION
    • Surveying recent developments in products liability discovery law and its implications
    • Highlighting tactical, cost-effective document production strategies
    • Explaining the interpretation and implication of the FRE and FRCP changes
    • Installing an effective e-discovery approach before problems arise
    • Discussing best practices and successful instances of preservation duties, litigation holds, technology challenges, e-discovery ethical dilemmas and budgeting issues
    • Making sure you have efficient attorney-client and work product privileges

David Bayer, Vice President, Stratify Inc.
Stephen D. Whetstone, Esq. Vice President, Client Development and Strategy, Stratify Inc.
Adam Landa, Principal, Greenberg Traurig LLP

2:45 NETWORKING AND REFRESHMENT BREAK
3:15 CREATING AN EFFECTIVE RECALL STRATEGY
    • Minimizing the damage as early as possible: knowing what to recall
    • Approaching damage control through effective coordination between different sectors of your business and working effectively with government controls and media connections
    • Examining compliance in the recall process
    • Appropriating the correct scope in relation to the various factors involved: geography, associated products, etc.
    • Navigating through the various government regulations and guidelines so as to prevent litigation in the future: avoiding the potential for double jeopardy

Mark Levy, Partner, Saul Ewing LLP
Sheila Heymeon-Heyer, Vice President of Global Regulatory Affairs, Boston Scientific

4:00 UNDERSTANDING LIABILITY RISK MANAGEMENT AND STRATEGY
    • Meeting FDA post-marketing surveillance requirements of accelerated approval
    • Monitoring and responding to adverse event reports and other signals: determining the when and whether to pull a drug from the market
    • Exploring the responses of prescribing to changes in labeling – do markets overreact?
    • Using risk metrics to identify underwriting opportunities
    • Making adequate risk disclosures in the underwriting process to prevent coverage disputes

Bruce Belzak, Head of Life Sciences, Marsh
Paul Hinton, Vice President, NERA Economic Consulting

5:00 END OF DAY 1

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Lowenstein Sandler is a nationally recognized AmLaw 200 law firm with over 250 attorneys in offices in New York and New Jersey. The Firm’s IP Group leverages the real world experience of its registered patent lawyers and prosecutors, who hold degrees in physics, chemistry, biology, electrical engineering, and mathematics, to provide clients with strategic legal and business advice. The Group’s clients include early-stage companies, venture funds, leading research universities and Fortune 100 corporations. Revered for its technical capabilities and track record, the Group has received top honors by the Chambers USA Guide to America’s Leading Lawyers for Business. Lowenstein Sandler - The Right Answer. www.lowenstein.com

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8:00  REGISTRATION AND BREAKFAST

8:15  CHAIRPERSON’S OPENING REMARKS

8:30  CRISIS FROM TYLENOL TO EPHEdra – LITIGATION, CRISIS & RECALLS: WHAT HAPPENS WHEN IT ALL GOES WRONG

- Effectively facing a hostile media in light of 24-hour news cycles, “gotha” career-seeking journalists, an explosive blogosphere, activist investors, and an NGO-Attorneys Generals- Plaintiff alliance
- Showing how pharmaceutical, biotech and medical device professionals need to think and work differently to protect the most valuable asset – the corporate brand – for their customers, investors and employees.
- Influencing the Court of Public Opinion
- Anticipating high profile matters before they strike
- Get legal and media teams to work together
- Avoiding the most common media mistakes

Richard Levick, President and CEO, Levick Strategic Communications

9:00  STRUCTURING AND ADMINISTERING MASS TORTS SETTLEMENTS

- Establishing effective terms and settlement criteria
- Conducting due diligence and data gathering before and during negotiation
- Addressing potential future claims and investigating fairness issues in tort settlement
- Determining the likely claim flow and claim universe
- Limiting duration while ensuring proficiency
- Funding options and management of assets
- Measuring and defining the risk of injury causation
- Negotiating and crafting the mass tort settlement agreement

Deborah Greenspan, Partner, Dickstein Shapiro LLP
Richard Silbert, Vice President and Associate General Counsel, Purdue Pharma
Lisa Warren, Associate General Counsel, Johnson & Johnson

9:45  NETWORKING AND REFRESHMENT BREAK

10:15  DISCUSSING PROCEDURAL TRENDS IN MDL, CAFA, AND STATE COURT CONSOLIDATED PROCEEDINGS

- Determining the impact of the Class Action Fairness Act in 2007 for the future
- Looking at the future of “forum shopping” and “coupon settlements”
- Examining the emergence of the consumer protection statutes as a means to attack the industry
- Determining when the best time to use MDL litigation is
- Understanding when and how to strategically negotiate settlements
- Examining the emergence of the consumer protection statutes as a means to attack the drug & medical device industry

Deborah Greenspan, Partner, Dickstein Shapiro LLP

11:00  EFFECTIVELY MANAGING MASS TORT LITIGATION AND CLASS ACTIONS

- Setting the strategy and coordinating cases with multiple plaintiffs
- Keeping your costs down, in regards to both in-house and outside counsel
- Making the decision to settle and devising strategies for successful settlements - the alternative dispute resolution (ADR) strategy
- Examining the impact of Cox-2 litigation
- Preambing the crisis: plan accordingly for potential crises’ in early stages
- Anticipate retaliatory responses by opposition
- Properly defining leadership structure to ensure clear communication

Honorable Judge Marina Corodemus (ret.), Director of ADR Practice, Corodemus & Corodemus LLC
Wendy Fleishman, Partner, Lieff, Cabraser Heimann & Bernstein, LLP
Glen J. Pogust, Partner, Kaye Scholer LLP

11:45  HIGHLIGHTING THE INTERSECTION OF GOVERNMENT INVESTIGATIONS

- Examining marketing practices that have allegedly resulted in hurting people
- Managing outside counsel efficiently
- Interfacing with compliance personnel regarding appropriate compliance policies and procedures
- Enforcing a comprehensive and constantly applied document retention policy
- Pointing out strategies to reduce fraud and abuse risks

Steve Sokolow, Associate General Counsel, Novartis Corporation
Edward Miller, Assistant General Counsel and Chief Compliance Officer, Boehringer-Ingelheim

12:30  SPEAKER AND DELEGATE LUNCHEON

1:30  MOCK DEMONSTRATION/DAUBERT HEARING

2 experienced attorneys will conduct a mock demonstration supervised by a judge. Have each side present a brief & oral argument. Follow this by having a judge rule and discuss on the presentation made by each side.

Presiding Judge: Honorable Susan Forsling, State Court of Georgia, Fulton County
Plaintiff Attorney: TBA
Defending Attorney: TBA

2:30  JUDGE’S PANEL - JUDICIAL VIEWS ON DECIDING CASES ON A FEDERAL/STATE LEVEL

- Overseeing an MDL case: effective strategies and perspectives from the other side of the bench
- New approaches and strategies to Daubert cases
- Highlighting alternative methods for deciding cases
- Effective use of ADR
- Examining coordination between federal and state courts

Honorable Susan B. Forsling, State Court of Georgia, Fulton County
Honorable Caroline S. Baker, State Court of Texas, Harris County; Honorable Arthur Boylan, US District Court of Minnesota

3:30  CLOSING REMARKS

At Saul Ewing, we are dedicated to the key values of excellence, energy and enthusiasm: excellence in our legal services, the energy to succeed, and an enthusiasm for understanding and being responsive to our clients’ needs. These core values are the hallmarks of our more than eight decades of service to clients. Saul Ewing is a Mid-Atlantic law firm that serves regional and national clients, providing them with a broad range of sophisticated legal services in complex, high-profile matters. With offices in Pennsylvania, Maryland, New Jersey, Delaware, the District of Columbia and New York, our regional footprint and established relationships with high-level decision-makers in the Mid-Atlantic region’s business, government, and legal realms uniquely position us to advise our clients on the region’s laws, policies, and practices.
Pre-Conference Workshops
Wednesday, October 24, 2007

8:30 am – 11:30 am
Determining Governing Factors for How and When to Use Scientific Evidence in Litigation Matters
Scientific evidence has become increasingly important in pharmaceutical litigation. The science underlying these matters has grown increasingly complex while the burdens on judges and juries have similarly increased. This workshop provides an opportunity to view how patent litigators prepare arguments relying on scientific evidence and how experts communicate sophisticated scientific principles to the lay person.

How you will benefit:
• Understand the role of the judge and jury in complex pharmaceutical litigation relying on complex scientific evidence;
• Hear how recent court decisions such as KSR and Pfizer v. Apotex will and have affected the role and importance of scientific evidence and expert testimony; and
• Learn the advice and best practices that will get now commonplace in pharmaceutical eDiscovery.

What we will cover:
• Case studies involving the use of scientific evidence;
• Legal aspects of scientific evidence including the Daubert factors; and
• How scientific evidence plays significant roles in major pharmaceutical litigation topics such as claim interpretation, infringement, novelty, enablement, and obviousness

Workshop Leaders:
Eyal H. Barash, Principal, Apretit Consulting
Howard Levine, Partner, Finnegan Henderson Farabow Garrett & Dunner LLP


11:30 am – 2:30 pm (Working Lunch to be Served)
Developing an Effective Compliance Program, Identifying Metrics, and Integrating Compliance with the FDA and Other Regulatory Bodies
Effective and accountable compliance programs can reduce legal exposure by identifying early risk areas while simultaneously reducing governmental scrutiny and providing additional defenses in litigation, both civil and criminal. This workshop will explore how to develop an effective compliance program, how to engage and ensure the participation of both executive and operational management, identify appropriate metrics to gauge compliance, and detail what to do when something goes wrong. While we will focus on compliance with U.S Food & Drug law and FDA regulation, we will also explore key examples and on how to integrate compliance with other federal regulatory bodies impacting regulated industry.

How you will benefit:
• Learn how to effectively structure compliance programs for maximum effectiveness
• Learn the importance of executive management integration into compliance management
• Understand the difference between structural compliance program elements versus substantive compliance requirements

What we will cover:
• A “Four Quadrant” compliance program framework for comprehensive enterprise compliance management
• Methods to engage executive management in detailed understanding of operational compliance issues and activities
• Managing compliance in an environment with multiple sets of regulatory requirements
• Governmental expectations for effective compliance program management
• Case studies and examples of ineffective compliance program execution and the collateral consequences of non-compliance

Workshop Leader:
John C. (Jack) Garvey, Esq., Vice President, Compliance & Quality Management, The Weinberg Group Inc.

Additional Speakers:
Michael A. Swit, Esq., Vice President, Life Sciences, The Weinberg Group Inc.


2:30 pm – 5:30 pm
Handling Xtreme eDiscovery Successfully
Hundreds of custodians. Terabytes of data. Multiple countries and languages. One production deadline for a government agency that will not accept any excuse. These nightmare scenarios are now commonplace in pharmaceutical eDiscovery. Learn the advice and best practices that will get you through them – from those who have lived it.

How you will benefit:
• Learn how to preserve electronic documents to comply with the new FRCP eDiscovery amendments and current case law
• Explore how to collect and process documents from multiple sources, in multiple countries, in multiple languages – including complex languages such as Chinese and Japanese – all in a forensically-sound manner
• Examine how advanced eDiscovery systems can save time and money – and save the day – on massive document collection reviews with tight deadlines

What we will cover:
• Advanced eDiscovery best-practices and features for fast, cost-effective reviews
• Planning for, drafting, distributing and following-up on litigation holds
• Best practices for forensic document collection
• Foreign language documents: technical and legal issues

Workshop Leaders:
David Bayer, Vice President, Stratify Inc.
Michael Goff, Director Foreign Client Development and Strategy, Stratify, Inc.
Stephen Whetstone, Esq., Vice President, Stratify Inc.

For more information about the speakers please visit: www.iqpc.com/legaliq

Pricing

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<td>Conference + 1 Workshop</td>
<td>$1,548</td>
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* A limited number of complimentary passes are available for qualified plan sponsors, foundations and endowments by calling 1-800-882-8684.

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(212) 201-4679

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Note: Contact venue for direction and transportation suggestions.

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Drug and Medical Device Litigation

2nd Conference on Drug and Medical Device Litigation
Managing Liability Through Proactive Preemption Strategies and Government Compliance
OCTOBER 24-26, 2007
THE WESTIN NEW YORK AT TIMES SQUARE, NEW YORK, NY