

American Conference Institute, creators of Drug and Medical Device Litigation, the annual December conference that has been the industry's premier product liability event for 13 years, brings you a unique and timely industry focus on the most powerful defense in product liability cases:

# DRUG & DEVICE PREEMPTION

*Eliminating product liability claims on the wholesale level in an evolving legal landscape*

July 14-15, 2008 | The Union League, Philadelphia, PA

Pre-Conference Workshop: Preemption Fundamentals | July 14, 2008 | 9:00 a.m. to 12:00 p.m.

ACI has gathered the premier drug and device preemption experts to analyze the current state of the law. Hear directly from the attorneys who have argued and briefed *Riegel, Kent, Levine, and Colacicco/McNellis*.

Distinguished Co-Chairs:



**James Beck**  
Counsel  
Dechert LLP



**Mark Herrmann**  
Partner  
Jones Day

Learn the practical implications of recent preemption case law, including how to:

- Present a strong preemption defense in the current legal landscape
- Determine when to raise the preemption defense
- Make the most of the FDA regulatory process when presenting your case
- Develop a regulatory process that incorporates preemption considerations
- Argue preemption in consumer protection, deceptive trade practices, and false advertising cases

Supporting Sponsor:

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Plus, One-Day Junk Science Summit on

## EXPERT WITNESS & SCIENTIFIC EVIDENCE

*The Complete Playbook for Challenging Experts and Communicating Complex Scientific Information to the Court*

(see pg. 10-11 inside)

JULY 16, 2008

Veteran drug and device litigators and jurists will share proven insights on:

- Communicating issues of a complex scientific and technical nature to the court
- Challenging expert credentials, scientific propositions and causation proof
- Preparing scientific and non-scientific witnesses for testifying at *Daubert* hearings and at trial

Distinguished Co-Chairs:



**Connie Matteo**  
Corporate Counsel—Litigation  
Wyeth



**Anand Agneshwar**  
Partner, Arnold & Porter LLP

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## Save millions by effectively using the preemption defense in drug and device cases...

Preemption is unquestionably the most powerful defense available to a drug or device manufacturer in product liability litigation because of its potential to eliminate all failure-to-warn claims involving a particular product. A win on preemption can save a company millions of dollars in litigation fees/discovery costs and potential jury awards. However, the uncertain state of preemption law at this time creates challenges to successfully asserting this defense.

### Preemption law is at a crossroads, threatening your ability to utilize the most inexpensive route to victory

The Supreme Court's silence on the issue of preemption is coming to an end. **The trilogy of cases granted certiorari during the 2008 term have the potential to change product liability litigation as we know it**, and the industry is anxiously awaiting the Court's final decision. While the win for device manufacturers in *Riegel* seemed to indicate that the Court would strongly uphold preemption in all three cases, the split decision in *Kent* dealt a **blow to pro-preemption advocates** and has left everyone guessing as to what the court will decide in *Levine* and what the Third Circuit will hold in the *Colacicco/McNellis* companion cases. Plus, a draft anti-preemption bill circulated on Capitol Hill would legislatively reverse *Riegel*. As the preemption law landscape changes, drug and device litigators and in-house counsel need to prepare for this pivotal time.

### An expert faculty will show you how to manage the changing preemption landscape as you seek dismissal of your cases

In order to successfully assert the preemption defense, litigators and in-house counsel need to know how to take full advantage of recent court rulings favoring preemption. Our faculty of preemption experts will analyze the nuances of recent decisions and provide their insights into how to use these cases effectively in future litigation. In addition, the faculty will examine **every possible outcome in the *Levine* case** to prepare you for what is sure to be a landmark decision. Also learn how preemption can be applied in non-failure to warn claims and get speakers' insights into what novel theories of liability plaintiffs' counsel may pursue next.

## Inadmissible Expert Testimony = No Causation = No Case

### Enhance your conference experience by also attending the one-day Junk Science Summit

After preemption, *Daubert* provides the next strongest weapon in the defense counsel's arsenal. Expert testimony and scientific evidence are the cornerstone of every products liability case. Although judges in both state and federal courts still struggle with their gatekeeping function under the *Daubert* (or equivalent) standard, if you can effectively prove the qualifications of your expert, as well as demonstrate the reliability of that opinion as it applies to the facts of your case, you can save your client **thousands, even millions of dollars** in *litigation costs, reputational damage, and lost revenue*. Jurisdictional standards vary and the stakes are high: the pressure is on you to dispel litigation as early on as possible. Learn from the experts who have litigated the drug and device industry's most high-stakes and high-publicity litigation in recent years, as they discuss with you strategies for effectively challenging the plaintiff's expert to defeat your opponent's case before it starts.

**This one-day junk science summit on Expert Witness and Scientific Evidence** will feature top-notch, experienced pharmaceutical and device defense litigators, who will discuss with you strategies that have worked in convincing judges to render an expert's opinion inadmissible when it counts most. An advanced, one-day conference specifically designed to present a forum for senior-level litigators to cross-fertilize and share best practices, this summit will provide you with proven insights to ensure your client's case does not progress beyond the *Daubert* hearing. The Summit will also include a **View from the Bench on Federal and State *Daubert* Standards**, which will feature a moderated discussion by jurists on how they weigh witness and scientific evidence when deciding for or against the admissibility of an expert's testimony.

Register now to ensure your place at what is sure to be a sold-out event. Call 1-888-224-2480, fax your registration form to 1-877-927-1563, or register online at [www.americanconference.com/preemption](http://www.americanconference.com/preemption) or [www.americanconference.com/junkscience](http://www.americanconference.com/junkscience)

# DRUG AND MEDICAL DEVICE PREEMPTION

## Distinguished Faculty

**The Honorable Michael M. Baylson**  
United States District Court Judge  
Eastern District of Pennsylvania (Philadelphia, PA)

**James Beck**  
Counsel  
Dechert LLP (Philadelphia, PA)

**Sheldon T. Bradshaw**  
Partner  
Hunton & Williams LLP (Washington, DC)

**The Honorable Charles R. Breyer**  
United States District Court Judge  
Northern District of California  
(San Francisco, CA)

**Julie Coletti**  
Counsel  
Bayer Corporation (Pittsburgh, PA)

**John Egan**  
Partner  
Rubin and Rudman LLP (Boston, MA)

**Perry Goldman**  
Vice President, Legal - Litigation  
Elan Pharmaceuticals (San Francisco, CA)

**David M. Gossett**  
Partner  
Mayer Brown LLP (Washington, DC)

**Mark Herrmann**  
Partner  
Jones Day (Chicago, IL)

**Michael X. Imbroscio**  
Partner  
Covington & Burling LLP (Washington, DC)

**J. Brian Jackson**  
Partner  
McGuireWoods LLP (Charlottesville, VA)

**David Klingsberg**  
Partner  
Kaye Scholer LLP (New York, NY)

**Jeffery A. Kruse**  
Senior Counsel  
Boston Scientific Corporation, CRM  
(St. Paul, MN)

**Eric G. Lasker**  
Partner  
Spriggs & Hollingsworth (Washington, DC)

**Scott M. Lassman**  
Partner  
Wilmer Cutler Pickering Hale and Dorr LLP  
(Washington, DC)

**David G. Martin**  
Vice President and Senior Counsel, Litigation  
Medtronic, Inc. (Minneapolis, MN)

**Thomas M. Parker**  
Partner  
Parker, Leiby, Hanna & Rasnick, LLC  
(Akron, OH)

**Timothy Pratt**  
Partner  
Shook Hardy & Bacon LLP (Kansas City, MO)

**Bert W. Rein**  
Partner  
Wiley Rein LLP (Washington, DC)

**Peter Rotolo**  
Partner  
Chaffe McCall LLP (New Orleans, LA)

**Jennifer L. Saulino**  
Attorney  
Covington & Burling LLP (Washington, DC)

**Paul W. Schmidt**  
Partner  
Covington & Burling LLP (Washington, DC)

**Caryn M. Silverman**  
Partner  
Sedgwick, Detert, Moran & Arnold LLP  
(New York, NY)

**Daniel E. Troy**  
Partner  
Sidley Austin LLP (Washington, DC)

**Anthony Vale**  
Partner  
Pepper Hamilton LLP (Philadelphia, PA)

**Chilton Davis Varner**  
Partner  
King & Spalding (Atlanta, GA)

**Robert Weiner**  
Partner  
Arnold & Porter LLP (Washington, DC)

**Malcolm Wheeler**  
Partner  
Wheeler Trigg Kennedy LLP (Denver, CO)

## EXPERT WITNESS AND SCIENTIFIC EVIDENCE SUMMIT

### Distinguished Faculty

**Anand Agneshwar**  
Partner  
Arnold & Porter LLP (New York, NY)

**Mark S. Cheffo**  
Partner  
Skadden, Arps, Slate, Meagher & Flom LLP  
(New York, NY)

**James J. Dillon**  
Partner  
Foley Hoag LLP (Boston, MA)

**Michael Dore**  
Member  
Lowenstein Sandler PC (Roseland, NJ)

**The Honorable Susan B. Forsling**  
Judge  
State Court of Fulton County Georgia  
(Atlanta, GA)

**Christy D. Jones**  
Chair, Pharmaceutical, Medical Device  
and Healthcare Industry Practice Group  
Butler, Snow, O'Mara, Stevens and Cannada,  
PLLC (Jackson, MS)

**The Honorable Richard Kramer**  
Superior Court Judge  
Superior Court of California,  
County of San Francisco  
(San Francisco, CA)

**Patricia E. Lowry**  
Partner, Squire, Sanders & Dempsey L.L.P.  
(West Palm Beach, FL)

**Connie Matteo**  
Corporate Counsel – Litigation  
Wyeth (Madison, NJ)

**Kevin Rosen**  
Chair, Healthcare and Life Sciences Practice  
Group, Gibson Dunn & Crutcher LLP  
(Los Angeles, CA)

**Stephen A. Ryan**  
Head, Medical Device and  
Pharmaceutical Litigation Practice  
Marshall Dennehey Warner Coleman  
& Goggin (King of Prussia, PA)

**The Honorable Norma L. Shapiro**  
Senior United States District Court Judge  
Eastern District of Pennsylvania  
(Philadelphia, PA)

**Robert K. Woo, Jr.**  
Partner  
King & Spalding (Atlanta, GA)

# Agenda-at-a-Glance

## Pre-Conference Workshop & Main Conference

Day One: Monday, July 14, 2008

## Main Conference

Day Two: Tuesday, July 15, 2008

## Junk Science Summit: Expert Witness & Scientific Evidence

Wednesday, July 16, 2008

Morning

8:00 Registration and Continental Breakfast for Pre-Conference Workshop

9:00 Pre-Conference Workshop Begins

8:00 Continental Breakfast

8:45 Co-Chairs' Opening Remarks

9:00 Strategically Developing and Litigating the Preemption Defense

10:15 Evaluating Whether or Not to Pursue a Preemption Defense

11:15 Morning Coffee Break

11:30 Creating Regulatory and Labeling Processes That Can Bolster the Preemption Defense

8:00 Registration and Continental Breakfast

8:30 Co-Chairs' Opening Remarks

8:45 Defending Against Causation Proof and Expert Witness Testimony: Successfully Challenging the Expert's Propositions, Credentials, and Credibility

10:15 Morning Coffee Break

10:30 Effective Strategies for Prepping and Utilizing Witnesses to Disprove the Plaintiff's Case

11:45 Luncheon Spotlight Address – View from the Bench on Federal and State *Daubert* Standards

Afternoon

12:00 Pre-Conference Workshop Ends and Registration for Main Conference Begins

1:00 Co-Chairs' Opening Remarks

1:15 The Preemption Defense for Medical Devices After *Riegel v. Medtronic*

2:30 Defending "Fraud on the FDA" Claims and Allegations in the Wake of *Warner-Lambert v. Kent*

3:45 Afternoon Coffee Break

4:00 Implied Preemption – Bracing for Potential Reform to Pharmaceutical Preemption Law

5:15 Countering Plaintiffs' Changes Being Effected (CBE) Arguments

6:15 Conference Adjourns to Day Two

12:15 Networking Luncheon

1:25 Asserting the Preemption Defense in Non-Warning Cases

2:15 View From the Bench – Judicial Perspectives on Preemption

3:15 Afternoon Coffee Break

3:30 Examining the FDA's Current Preemption Goals and Priorities

4:15 Contemplating the Congressional/Political Response to Drug and Device Preemption

5:00 Conference Concludes

1:15 Effectively Translating and Communicating Complex Scientific and Technical Evidence to the Judge and Jury

2:30 Afternoon Refreshment Break

2:45 Strategies from the Trenches: Managing Multiple Experts and Coordinating with Co-Counsel During Complex Drug and Device Litigation

4:00 Keeping Abreast of Current Judicial Standards, Case Law, and Other Initiatives Affecting the Admissibility of Expert Witnesses and Scientific Evidence

5:00 Summit Concludes

## Who You Will Meet

### In-house counsel and regulatory executives for:

- pharmaceutical companies
- medical device companies
- biotech companies

### Attorneys with practice areas in:

- pharmaceuticals
- drug and medical devices
- products liability
- mass tort
- complex and multidistrict litigation
- healthcare

### In-house counsel, claims professionals, and risk managers for:

- insurance companies
- risk retention groups
- captives

## COVINGTON

COVINGTON & BURLING LLP

Covington and Burling LLP integrates transactional, regulatory and intellectual property expertise to meet the specialized needs of life sciences companies in the United States, Europe and around the world. 170 lawyers actively practice in our life sciences industry group and provide a full range of transactional and advisory services to pharmaceutical, biotechnology, medical device, food, organic, veterinary, cosmetic and agricultural companies throughout the world. The group is also comprised of members of our corporate, litigation, intellectual property, competition and trade practices.



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For more information about this program or our global portfolio of events, please contact:

*Wendy Tyler*

Group Leader & Business Development Executive  
American Conference Institute

Tel: 212-352-3220 x242 | Fax: 212-220-4281  
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### About the Venue

The Union League, which occupies an entire city block in the center of Philadelphia's commercial and cultural district, is a shining jewel of history in a city defined by

such treasure. Founded in 1862 as a patriotic society to support the policies of President Abraham Lincoln, The Union League has hosted U.S. presidents, heads of state, industrialists, entertainers and visiting dignitaries from around the globe. The classic French Renaissance-styled League House, with its brick and brownstone façade and dramatic twin circular staircases leading to the main entrance, is listed in the National Historic Register, and dates back to 1865, when the Broad Street building was completed. Adorning the walls and hallways is the League's distinguished art collection, artifacts imbued with the heritage and culture of its membership. The collection is a rich, historical chronicle of Philadelphia's unique imprint upon the American landscape from the nineteenth century to today.



### About American Conference Institute

American Conference Institute (ACI) along with our sister organization based in London, C5 Conferences, monitors trends and developments in every major industry with a view to providing timely and leading edge information to our delegates. With over 600 conferences in North America, Europe, the Commonwealth of Independent States (CIS) and China, ACI/C5 Conferences provide a diverse portfolio of first class events that is tailored to the senior level executive spanning multiple industries and geographies. Produced by former in house and outside counsel as well as some of the industry's most seasoned professionals, ACI's production team sets the benchmark for quality in content. Our conferences and courses cover current legal issues in business for both the public and private sectors, including: Litigation, Insurance, Employment, Administration, Corporate Finance and Securities, Bankruptcy and Insolvency, Intellectual Property, Cross Border and International Transactions, Energy, Environment, Real Estate and Construction.

# DRUG & DEVICE PREEMPTION

MONDAY, JULY 14, 2008  
PRE-CONFERENCE WORKSHOP

9:00 A.M. TO 12:00 P.M.  
(REGISTRATION OPENS AT 8:00 A.M.)

## PREEMPTION FUNDAMENTALS

### John Egan

Partner  
Rubin and Rudman LLP (Boston, MA)



### Peter Rotolo

Partner  
Chaffe McCall LLP (New Orleans, LA)

- Identifying and defining the different types of preemption
  - express
  - implied
    - field
    - conflict
- Recognizing the basis for drug and device preemption
- Understanding the presumption against preemption and how it has been applied in drug and device litigation
- Tracking the history of preemption in drug and device liability litigation
  - where is preemption succeeding and failing?
  - are any patterns emerging?
- Applying preemption decisions in other industries to the drug and device industries
- Understanding the interplay between preemption and the FDA regulatory process
  - how is the FDA administered?
  - how does a product move through the FDA approval process?

MAIN CONFERENCE  
(REGISTRATION OPENS AT 12:00 P.M.)

1:00  
Co-Chairs' Opening Remarks



### James Beck

Counsel  
Dechert LLP (Philadelphia, PA)



### Mark Herrmann

Partner  
Jones Day (Chicago, IL)

1:15  
The Preemption Defense for Medical Devices  
After *Riegel v. Medtronic*



### David M. Gossett

Partner  
Mayer Brown LLP (Washington, DC)



### David G. Martin

Vice President and Senior Counsel, Litigation  
Medtronic, Inc. (Minneapolis, MN)



### Daniel E. Troy

Partner  
Sidley Austin LLP (Washington, DC)

- Understanding *Medtronic Inc. v. Lohr* and its effect on preemption for non-PMA medical devices
- Analyzing the Supreme Court's definition of "requirement" and its effect on preemption
- Exploring *Riegel* and its effect on preemption for Class III PMA-approved devices
  - how does the decision impact medical device product liability cases going forward?
  - examining the effect of the Court's declining to address "parallel" violation claims – did plaintiffs profit from their own waiver?
  - does the decision apply retroactively and/or to pending cases?
- Reassessing the preemption analysis for PMA variants post-*Riegel*
  - PMA supplement devices
  - down-classified PMA devices
  - product development protocol and transitional devices
- Does *Riegel* apply to non-PMA devices?
  - 510K devices
  - investigational devices
  - humanitarian device equipment
- Can implied preemption arguments be applied to medical devices in light of the *Riegel* decision?
  - when to use the PMA approval process versus the 510K approval process
- Preparing for "parallel" violation claims
  - the importance of internal company record keeping
  - the FDA's exclusive prosecutorial authority
  - proving violation claims are not really "parallel" but actually conflict with FDA regulations
- Setting up dispositive motions against allegedly "parallel" violation claims

2:30

Defending "Fraud on the FDA" Claims and  
Allegations in the Wake of *Warner-Lambert v. Kent*



### James Beck

Counsel  
Dechert LLP (Philadelphia, PA)



### David Klingsberg

Partner  
Kaye Scholer LLP (New York, NY)

- The basics – what is the effect of a 4-4 tie?
- Understanding the precursor to *Kent* – *Buckman Co. v. Plaintiff's Legal Committee*
  - how *Buckman* came about
  - the effect of the government's position in *Buckman*
  - emphasizing the inherent conflict at the core of fraud on the FDA
  - applying *Buckman* – how *Buckman* was received by the courts
- Differentiating the *Buckman* and *Kent* cases

- legal and factual factors that contributed to disparate results
- what lessons can be drawn from *Kent*?
- addressing the concerns raised by the Justices at the *Kent* oral argument
- the effect of the government's position in *Kent*
- Analyzing how the *Kent* decision will effect "fraud on the FDA" allegations
- Examining the practical implications of the Second and Sixth Circuit Court split
  - preparing for increased forum shopping
  - MDL strategy
  - effect of fraud on the FDA claims on the FDA – can these effects be empirically established?
- What specific state laws are affected by the decision?
- Approaching "fraud type" allegations that are not outright "fraud on the FDA" claims
  - preventing Plaintiffs from introducing "fraud on the FDA" evidence
- Exploring the possibility of an exception for fraud on the FDA if the FDA has found fraud

## 3:45 Afternoon Refreshment Break

## 4:00 Implied Preemption – Bracing for Potential Reform to Pharmaceutical Preemption Law



**Mark Herrmann**  
Partner  
Jones Day (Chicago, IL)



**Robert Weiner**  
Partner  
Arnold & Porter LLP (Washington, DC)



**Paul W. Schmidt**  
Partner  
Covington & Burling LLP (Washington, DC)

- Examining the implications of the 2006 FDA "Preemption Preamble" on implied preemption
  - how much deference can be given to the preamble of a regulation?
  - how much deference is being given to the FDA?
  - what retroactive effect, if any, does the preamble have on claims accruing or asserted prior to the preamble?
- Evaluating the current status of implied preemption cases in state and federal courts
- Does any presumption against preemption apply to implied preemption cases?
- Presenting a strong preemption defense in the current legal landscape
  - what factors bolster the preemption defense?
- How can generics use the preemption defense?
  - working together with innovator companies to defend the product
- Predicting the Supreme Court's holding in *Wyeth v. Levine*
  - examining how elements of the *Riegel* decision may carry over to *Levine*
    - deference given to the FDA
    - dictum suggesting preemption for drugs is still open

- similarity of the Court's description of the PMA process to the FDA approval process for new drugs
- Justice Ginsburg's dissent
- What can be inferred from the split decision in *Kent*?
  - deference given to the FDA – will it matter anymore – should it?
- After *Levine*: what novel theories of liability will Plaintiffs pursue?
  - violation claims
  - consumer fraud claims
  - economic injury claims
  - nuisance claims

## 5:15 Countering Plaintiffs' Changes Being Effectuated (CBE) Arguments



**Bert W. Rein**  
Partner  
Wiley Rein LLP (Washington, DC)



**Malcolm Wheeler**  
Partner  
Wheeler Trigg Kennedy LLP (Denver, CO)



**Jennifer L. Saulino**  
Attorney  
Covington & Burling LLP (Washington, DC)

- Clarifying the scope of the CBE provision
  - understanding the administrative history of CBE regulations
  - to what extent do companies have discretion to modify labels?
    - how do these types of changes affect preemption?
  - interpreting "new" risk information
  - how should companies treat newly discovered safety information?
- Exploring the implications of *Riegel* for CBE arguments
- Examining FDA's proposed amendments to the "Changes Being Effectuated" regulations and Congress' push to resolve the issue
- Surveying Plaintiffs' success in using the CBE provision to circumvent the FDA approval argument
- Effectively refuting Plaintiffs' claims that manufacturers can make label changes at any time

## 6:15 Conference Adjourns to Day 2

TUESDAY, JULY 15, 2008

## 8:00 Continental Breakfast

## 8:45 Co-Chairs' Opening Remarks

## 9:00 Strategically Developing and Litigating the Preemption Defense



**Eric G. Lasker**  
Partner  
Spriggs & Hollingsworth (Washington, DC)

# DRUG & DEVICE PREEMPTION



## Chilton Davis Varner

Partner

King & Spalding (Atlanta, GA)

- Choosing a preemption case wisely
  - identifying which cases are good candidates
  - biting the bullet in cases that are poor candidates
- Strategies for filing preemption motions
  - determining when to raise the preemption defense
    - motion to dismiss vs. motion for summary judgment
    - 12(b)(6) motion
  - determining the claims against which to raise the preemption defense
    - assessing the benefits and drawbacks of appealability
- Presenting the regulatory evidence
  - proving the FDA knew about adverse events and approved the label without warnings
    - demonstrating the document trail between the company and the FDA
  - collecting and organizing company evidence to debunk violation claims
  - using FDA laws, regulations and position statements
  - using former FDA employees as witnesses
- Admitting evidence of the manufacturer's diligence during label negotiations after a preemption motion has been lost
- Crafting preemption arguments for situations where there is no obvious comment from the FDA
  - making the most of the FDA approval process throughout the case
- Overcoming judicial bias towards the preemption defense
  - convincing the court of the legitimate public policy reasons for preempting plaintiff's claims
- Convincing a skeptical jury to accept the validity and authority of the FDA approval process
  - combating a negative, public perception of the FDA
  - dealing with GAO reports that criticize the agency
  - dealing with recent amendments to the FDCA

## 10:15

### Evaluating Whether or Not to Pursue a Preemption Defense

#### Perry Goldman

Vice President, Legal - Litigation

Elan Pharmaceuticals (San Francisco, CA)



#### Timothy Pratt

Partner

Shook Hardy & Bacon LLP (Kansas City, MO)



#### Anthony Vale

Partner

Pepper Hamilton LLP (Philadelphia, PA)

*This session will present several hypotheticals involving different products and different levels of regulatory involvement. Panelists will provide a practical approach for conducting a "preemption assessment" and examine which factors should be considered when determining whether or not a case is a good fit for preemption. Points of discussion will include:*

- Developing an assessment process to determine if the preemption defense can be successfully raised

- What type of regulatory action is needed for a good preemption defense?
- What are the theoretical and practical limits of preemption?

## 11:15

### Morning Coffee Break

## 11:30

### Creating Regulatory and Labeling Processes That Can Bolster the Preemption Defense



#### Jeffery A. Kruse

Senior Counsel

Boston Scientific Corporation, CRM (St. Paul, MN)



#### Michael X. Imbroscio

Partner

Covington & Burling LLP (Washington, DC)

- Restructuring regulatory processes in light of recent Supreme Court and federal circuit decisions
- Taking advantages of FDAAA regulatory changes
- Developing a regulatory process that incorporates preemption considerations
  - increasing interaction with the FDA
  - building a regulatory record
    - how many warnings should be submitted to the FDA?
    - when should warnings be submitted?
    - obtaining a definitive ruling from the FDA
  - wording labels in a manner that will pose the least risk
  - involving non-regulatory departments in regulatory procedures
  - recordkeeping to establish day-to-day compliance with good manufacturing processes and other FDA regulations
  - conducting risk assessments throughout the process
- Adding legal oversight to the regulatory process
  - what is and what should be legal's role?
- Post-market risk management and label maintenance
- Working with the marketing department to achieve economic goals while limiting the company's liability exposure
- Addressing warning letters, Forms 483 and other Agency indications of regulatory non-compliance
- Creating a training program that explains preemption to others within the company and to foreign colleagues

## 12:15

### Networking Luncheon

## 1:25

### Asserting the Preemption Defense in Non-Warning Cases

#### Julie Coletti

Counsel

Bayer Corporation (Pittsburgh, PA)



#### J. Brian Jackson

Partner

McGuireWoods LLP (Charlottesville, VA)



#### Caryn M. Silverman

Partner

Sedgwick, Detert, Moran & Arnold LLP (New York, NY)

# Eliminating product liability claims on the wholesale level in an evolving legal landscape

- Assessing the implications of the Supreme Court preemption trilogy outside of the product liability sphere
  - will the expansion of deference to the FDA go beyond labeling?
- Arguing preemption in consumer protection, deceptive trade practices and false advertising cases
  - surveying state consumer statutes
  - safe harbor provisions
  - *Pennsylvania Employees Benefit Trust Fund, et al. v. Zeneca Inc.*
- Using the preemption defense in cases brought by State Attorneys General
  - employing older preemption cases (irrespective of product or industry) to set forth the basic principles of preemption jurisprudence
  - expanding preemption beyond state AG cases involving labeling issues to cases involving marketing activities and other activities regulated by the FDA
- FDCA negligence per se claims
- Asserting preemption in off-label communications cases
- Employing preemption in cases brought by third party payors
- Preemption in cases alleging public nuisance

## 2:15 View From the Bench – Judicial Perspectives on Preemption

**The Honorable Michael M. Baylson**  
United States District Court Judge  
Eastern District of Pennsylvania (Philadelphia, PA)



**The Honorable Charles R. Breyer**  
United States District Court Judge  
Northern District of California (San Francisco, CA)

### Moderator:



**Thomas M. Parker**  
Partner  
Parker, Leiby, Hanna & Rasnick, LLC (Akron, OH)

*The current state of preemption jurisprudence for the drug and device industries is in a holding pattern as we await the Supreme Court's decision in Wyeth v. Levine. The lack of consistency and the uncertainty surrounding preemption often makes it difficult for a defendant to assess how to proceed in product liability litigation. Renowned federal jurists experienced in mass tort products liability litigation and prescription drug and device-related litigation will provide their insights into preemption for the drug and device industries. Learn what effect the Riegel and Kent decisions will have on their interpretations of the preemption defense. The judges will also discuss the practical issues arising out of claims that a device was not manufactured in compliance with FDA requirements.*

## 3:15 Afternoon Refreshment Break

## 3:30 Examining the FDA's Current Preemption Goals and Priorities



**Sheldon T. Bradshaw**  
Partner  
Hunton & Williams LLP (Washington, DC)  
(former Chief Counsel, FDA)

*At the core of the drug and device preemption debate is the extent of the FDA's authority to approve prescription medical products and to control their labeling. Since 1991, the FDA has weighed in on this issue and has presented its position on preemption through amicus briefs in several Supreme Court cases. In addition, the "preemption preamble" to the 2006 drug labeling final rule and the proposed change to the CBE regulations further solidify the FDA's stance on preemption. This session will provide insights into how the FDA has developed its current position and how the changing preemption landscape will affect the agency. Topics of discussion will include:*

- Charting the evolution of the FDA's position on preemption
- Examining the FDA's position in *Riegel*, *Kent*, and *Levine*
- Weighing the impact of the *Riegel* and *Kent* decisions on the FDA's position on preemption
- Preserving agency credibility – how much can the FDA change its preemption-related positions in a new administration?

## 4:15 Contemplating the Congressional/Political Response to Drug and Device Preemption



**Scott M. Lassman**  
Partner  
Wilmer Cutler Pickering Hale and Dorr LLP  
(Washington, DC)

*In addition to monitoring how preemption is faring at the state, federal and Supreme Court levels, it will also be important to keep an eye on initiatives at the Congressional level. While the Supreme Court decisions on preemption may have a profound effect on drug and device product liability litigation, political and Congressional activities may produce even greater change. Legislative experts will consider how Congress will react to the Supreme Court preemption decisions and how the 2008 elections may affect the preemption debate.*

## 5:00 Conference Concludes

## Continuing Legal Education Credits



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ACI has gathered a distinguished faculty of drug and device litigators who are experts on the use and admissibility of expert witnesses and scientific evidence in the defense of products liability claims. Attorneys speaking at this unique summit have been involved in litigation concerning PPA, COX-2, Vioxx, HRT, Ephedra, OxyContin, Paxil, silicone breast implants, asthma medications, medical devices, contraceptives, vaccines, biologics, antiseptic drugs, psychopharmaceutical drugs, over-the-counter-medications *and many others...*

**8:00**  
**Registration and Continental Breakfast**

**8:30**  
**Co-Chairs' Opening Remarks**



**Connie Matteo**  
Corporate Counsel – Litigation  
Wyeth (Madison, NJ)



**Anand Agneshwar**  
Partner  
Arnold & Porter LLP (New York, NY)

**8:45**  
**Defending Against Causation Proof and Expert Witness Testimony: Successfully Challenging the Expert's Propositions, Credentials, and Credibility**



**Mark S. Cheffo**  
Partner  
Skadden, Arps, Slate, Meagher & Flom LLP (New York, NY)



**James J. Dillon**  
Partner  
Foley Hoag LLP (Boston, MA)

Credential Methodology and Expert Fitness

- Investigating expert credentials with an eye towards establishing fertile ground for cross-examination
- Evaluating whether the expert is qualified to make the opinions being made, particularly when construing FDA and other regulations at issue in the case
- Tips for effectively dissecting scientific evidence depositions
- Exploiting the dichotomy between “practicing” and “academic” experts
  - is or was the expert involved in ongoing studies of the product at issue?
  - getting behind the science to evaluate the quality and reputation of the expert’s publishing record
    - challenging the quality of the peer-review – determining what the acceptable standard is in the industry regarding published literature
    - determining the true quality and industry reputation of a publishing journal - is the journal actually “peer-reviewed” or is it a “vanity press?”

Witness Propositions

- Responding to witness propositions (on paper and in court) that a drug or device caused a specific negative medical outcome
  - questioning the state of scientific evidence – is the opinion being offered generally accepted in the community (now and during the time frame at issue)

- challenging the level, quality, soundness, and worthiness of the evidence – evaluating factors that weigh into methodology determinations
- differentiating your approach to confronting the witness at the *Daubert* stage vs. during litigation
- parsing “substantial contributing factor” in causation and differential diagnoses
- Analyzing credential methodology and expert fitness for a particular case

**10:15**  
**Morning Refreshment Break**

**10:30**  
**Effective Strategies for Prepping and Utilizing Witnesses to Disprove the Plaintiff's Case**



**Stephen A. Ryan**  
Head, Medical Device and Pharmaceutical Litigation Practice  
Marshall Dennehey Warner Coleman & Goggin  
(King of Prussia, PA)



**Christy D. Jones**  
Chair, Pharmaceutical, Medical Device and Healthcare Industry Practice Group  
Butler, Snow, O’Mara, Stevens and Cannada, PLLC  
(Jackson, MS)

- Making strategic decisions regarding the timing and involvement of experts
- Narrowing down causation issues by effectively utilizing experts as consultants early on in litigation
- Keeping track of information that is communicated to the expert for privilege purposes
- Coordinating multiple experts and working with “science” counsel when defending against mass tort litigation in multiple jurisdictions
- Structuring testimony for court – discussing potential subjects for direct and cross-examination
- Evaluating the expert’s prior testimony and consulting record to evaluate and establish –
  - expertise in specific subject matter through practice, publication or research
  - conflicts of interest that may arise out of ties to the industry and the parties involved in the litigation
- Advanced strategies for handling expert witnesses on the stand
- Ethical obligations of counsel when handling and utilizing experts in drug and device litigation
  - how should conversations between the expert and the lawyer be treated?
  - unique considerations when managing multi-jurisdictional litigation involving national and local counsel and experts

# The Complete Playbook for Challenging Experts and Communicating Complex Scientific Information to the Court

11:45

## Luncheon Spotlight Address – View from the Bench on Federal and State *Daubert* Standards



### The Honorable Norma L. Shapiro

Senior District Court Judge  
United States District Court, Eastern District of Pennsylvania  
(Philadelphia, PA)



### The Honorable Richard Kramer

Superior Court Judge  
Superior Court of California, County of San Francisco  
(San Francisco, CA)



### The Honorable Susan B. Forsling

Judge  
State Court of Fulton County Georgia (Atlanta, GA)

#### Discussion Moderated by:



### Robert K. Woo, Jr.

Partner  
King & Spalding (Atlanta, GA)

*Enjoy an interactive discussion over lunch as Judges Shapiro, Kramer and Forsling provide insights into what factors federal and state judges consider when evaluating a Daubert or equivalent challenge. Learn how judges interpret and analyze your expert and scientific testimony and what level and standard of proof is expected when challenging an expert. Hear from judges who have issued rulings on the admissibility of expert testimony, and be prepared with your most pressing questions to get the most out of this interactive session.*

1:15

## Effectively Translating and Communicating Complex Scientific and Technical Evidence to the Judge and Jury



### Kevin Rosen

Chair, Healthcare and Life Sciences Practice Group  
Gibson Dunn & Crutcher LLP (Los Angeles, CA)



### Michael Dore

Member  
Lowenstein Sandler PC (Roseland, NJ)

- Explaining scientific, technical, and medical jargon to the court in a manner that will facilitate easy comprehension and retention of information, including –
  - epidemiological principles
  - toxicology reports
  - statistical data and damages calculations
  - technical information and terms of art
- Persuading the judge and jury to carefully consider adverse event reports, data obtained from clinical trials, and other publicly published medical literature
- Putting into plain words the “community understanding” of the use and applicability of a product as recognized by industry practitioners during the time the product was on the market
- Communicating a clear message to the jury by utilizing demonstratives and graphics at trial that simplify information
- The use of “Science Days” to provide courts with background information about complex scientific issues.

2:30

## Afternoon Refreshment Break

2:45

## Strategies from the Trenches: Managing Multiple Experts and Coordinating with Co-Counsel During Complex Drug and Device Litigation



### Anand Agneshwar

Partner  
Arnold & Porter LLP (New York, NY)



### Connie Matteo

Corporate Counsel – Litigation  
Wyeth (Madison, NJ)

*During this session, Connie and Anand will discuss with you what strategies they have used to successfully challenge the plaintiff's experts, ensure they had the “right” experts, and present complex scientific and technical information to the judge and jury. Hear directly from these experienced trial counsel regarding how they interacted with co-counsel in mass cases to attack the plaintiff's witnesses and evidence, as well as prepare company, consulting, and testifying witnesses for court.*

4:00

## Keeping Abreast of Current Jurisdictional Standards, Case Law, and Other Initiatives Affecting the Admissibility of Expert Witnesses and Scientific Evidence



### Patricia E. Lowry

Products Liability and Mass Tort Practice Group Leader  
Squire, Sanders & Dempsey L.L.P. (West Palm Beach, FL)



### Robert K. Woo, Jr.

Partner  
King & Spalding (Atlanta, GA)

During this session, you will be brought up to date on:

- The past year's *Daubert* and *Frye* cases regarding general causation for the drug and device industry
- Current status of other issues relating to general causation in drug and device litigation
  - Epidemiology versus other forms of proof
  - Relative risks greater than or less than 2.0
- Disclosure requirements
  - Company witnesses
  - Treating physicians
- Additional effects of recent pharmaceutical and device cases and settlements on the admissibility and use of expert witness testimony and scientific evidence during litigation

5:00

## Conference Adjourns

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American Conference Institute, creators of Drug and Medical Device Litigation, the annual December conference that has been the industry's premier product liability event for 13 years, brings you a unique and timely industry focus on the most powerful defense in product liability cases:

# DRUG & DEVICE PREEMPTION

*Eliminating product liability claims on the wholesale level in an evolving legal landscape*

July 14-15, 2008 | The Union League, Philadelphia, PA

## Plus, One-Day Junk Science Summit on EXPERT WITNESS & SCIENTIFIC EVIDENCE

*The Complete Playbook for Challenging  
Experts and Communicating Complex Scientific  
Information to the Court*

JULY 16, 2008

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<input type="checkbox"/> Expert Witness & Scientific Evidence Summit (676L08-PHI)	\$1095	\$1195	\$1395
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American Conference Institute is pleased to offer our delegates a limited number of hotel rooms at a preferential rate. Please contact the hotel directly and mention the "ACI – DRUG AND DEVICE PREEMPTION" conference or "ACI – EXPERT WITNESS & SCIENTIFIC EVIDENCE SUMMIT" to receive this rate:

VENUE: The Union League  
ADDRESS: 140 South Broad Street, Philadelphia, PA 19102  
RESERVATIONS: 215-587-5570

#### Registration Fee

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