PRESENTED BY

ABA Tort Trial & Insurance Practice Section’s Products Liability Committee and Drug, Device, & Biotechnology Subcommittee
Co-sponsored by the ABA Section of Litigation’s Product Liability Committee Biotech Subcommittee and the Section of Science & Technology Law’s Biotechnology Committee and Food, Cosmetics & Nutraceuticals Committee
AGENDA

This course is expected to qualify for 7 CLE credit hours for California.

8:00 a.m. – 8:30 a.m.  CONTINENTAL BREAKFAST

8:10 a.m. – 8:15 a.m.  WELCOME & INTRODUCTION

8:15 a.m. – 8:55 a.m.  Regulatory Strategies for Life Science Companies

Developing successful regulatory strategies helps clients maximize their commercial opportunities while minimizing risk. Cultivating regulatory pathway and post-market strategies and understanding the critical importance of monitoring and revising those strategies are significant factors in avoiding the pitfalls and consequences of the ever-changing regulatory environment. These speakers will examine vital regulatory strategy subjects, regulatory standards, and risk tools for use with clients.

Speakers

Krista Carver  
Covington & Burling LLP  
Washington, D.C.

Kai Peters  
Gordon & Rees  
San Francisco, CA

8:55 a.m. – 9:25 a.m.  Minimizing the Risk of Off Label Promotion Claims

All life science companies face the risk of criminal or civil actions alleging improper off label use promotion. This speaker will address the scope of the existing off-label promotion prohibitions, ways to minimize the risks of such improper off label promotion claims, and effectively defending litigation involving these allegations.

Speaker

Michael K. Brown  
Reed Smith  
Los Angeles, CA

9:25 a.m. – 10:00 a.m.  What’s on the Horizon? Emerging Legal Trends

This presentation will address emerging issues and legal trends, and look at what developments are anticipated in the future.

Speakers

Mathew dos Santos  
Counsel, Litigation and Information Risk Management  
Jazz Pharmaceuticals, Inc.  
Palo Alto, CA

Madeleine McDonough  
Shook, Hardy & Bacon L.L.P.  
Washington, D.C.

10:00 a.m. – 10:10 a.m.  BREAK
10:10 a.m. – 11:00 a.m. **The FDA and Preemption**

The blockbuster Supreme Court decisions in *Mensing* and *Bartlett* continue to be interpreted and applied by state and federal courts. These attorneys will address the current state of the preemption defense in light of these landmark cases.

**Speakers**

- **Carolyn Taylor**  
  Morris Polich & Purdy LLP  
  San Diego, CA
- **Habib Nasrullah**  
  Wheeler Trigg O’Donnell  
  Denver, CO
- **Steven J. Skikos**  
  Skikos, Crawford, Skikos & Joseph  
  San Francisco, CA

11:00 a.m. – 12:00 p.m. **Best Practices in Coordinating Mass Tort Litigation**

This panel of federal and state court judges, an experienced mediator/discovery referee, and representatives of both sides of the bar will discuss their experiences and best practices in handling key discovery, settlement, and litigation of coordinated and pattern drug and device mass tort litigation.

**Moderators**

- **Khaldoun Baghdadi**  
  Walkup, Melodia, Kelly, & Schoenberger  
  San Francisco, CA
- **Michael Healy**  
  Sedgwick LLP  
  San Francisco, CA

**Panel**

- **Hon. Paul Singh Grewal**  
  Northern District of California
- **Catherine A. Yanni**  
  JAMS San Francisco
- **Hon. Richard A. Kramer**  
  San Francisco Superior Court
- **Hon. George Hernandez**  
  Alameda Superior Court

12:00 p.m. – 1:00 p.m. **LUNCH**

1:00 p.m. – 1:30 p.m. **Innovator Liability Developments**

This presentation will address how innovator liability theories have fared in the five years since *Conte*, and will evaluate where these theories are headed.

**Speaker**

- **William Hoffman**  
  Kaye Scholer  
  Washington, D.C.

1:30 p.m. – 2:00 p.m. **Litigating in Federal Court: Removals, Daubert, and MDL Strategies**

These speakers will address key developments in removal jurisprudence which enhance the ability to get cases to federal court, and also evaluate
developments and considerations when you get to federal court, including Daubert and MDL strategies.

Speakers

Brendan Ford  
K&L Gates  
Orange County, CA

Lori B. Leskin  
Kaye Scholer  
New York, NY

2:00 p.m. – 2:50 p.m.

The Inside View: Implementing Meaningful Diversity and Inclusion Policies and Practices

This panel will discuss the value of meaningful diversity and inclusion policies and initiatives, and outline effective approaches to achieving concrete and measurable results.

Moderator

Alicia Donahue  
Shook, Hardy & Bacon L.L.P.  
San Francisco, CA

Panel

Ellen Rosenthal  
Chief Counsel Pfizer Legal Alliance, VP & Assistant General Counsel Pfizer Inc.  
New York City, NY

G. Eric Davis  
Senior Vice President, General Counsel BioMarin Pharmaceutical Inc.  
Novato, CA

Melanie Gross  
Senior Corporate Counsel Genentech, Inc.  
South San Francisco, CA

2:50 p.m. – 3:00 p.m.

BREAK

3:00 p.m. – 3:40 p.m.

Negotiating an Effective Clinical Trial Agreement and Limiting Litigation Exposure

Clinical research is the lifeblood of the life sciences industry, and clinical trial agreements dictate the terms and conditions among the sponsor, institution and investigator. The agreements must be entered into knowingly, effectively and efficiently. Many issues (for example, injury compensation, insurance, study registration and results publication) need to be addressed in these agreements and should be considered carefully to avoid delays or unwanted or unintended consequences. These speakers will discuss how clinical trial agreements can be negotiated, and what potential obstacles to be aware of.

Speakers

Mary Ellen Allen  
Senior Corporate Counsel Genentech, Inc.  
South San Francisco, CA

Elaine Tseng  
King & Spalding  
San Francisco, CA
3:40 p.m. – 4:20 p.m. Medical Device Regulatory Compliance & Recall
How well a company manages a recall situation or deals with regulatory non-conformity matters, as outlined in a 483 or FDA Warning Letter, can affect not only the future viability of the product, the company’s liability, and financial loss, but can also affect a company’s good name, reputation, and “brand equity.” These speakers will address the key issues to consider and strategies to implement for an effective compliance and recall program.

Speakers
Jorge A. Ochoa, Ph.D., P.E.
Exponent
Menlo Park, CA
Carrie Kuehn, M.P.H., RAC
Exponent
Menlo Park, CA
Greg Jackson
Bowman and Brooke
San Diego, CA

4:20 p.m. – 4:50 p.m. Emerging Intellectual Property Issues
Intellectual property is essential to the success of life science companies. For established companies, the market exclusivity offered by patent protection is a critical component to justify the tremendous investment in the research and development of products. For start-up companies, strong patents are essential to generate financing, and to advance research. Intellectual property laws and the US patent system are monitored closely by the life sciences industry. This speaker will present an overview of patent reform initiatives, recent intellectual property case law developments and discuss the impact those developments have on life sciences.

Speaker
April Abele
Goodwin Proctor
San Francisco, CA

4:50 p.m. – 5:20 p.m. Regulatory and Litigation Issues for Biological Products Post-Approval
These speakers will provide background on the nature of biologic products including the differences from more traditional small molecule therapeutics, the pharmacovigilance challenges and the complexities in the manufacturing processes. They will discuss the regulatory and litigation risks for these products including the anticipated abbreviated approval pathway for “biosimilar” drugs as well as the anticipated increase in diagnostic regulations.

Speakers
Krista L. Cosner
ABA Pharmaceutical Subcommittee Chair
San Francisco, CA
Steven M. Weisman
Global Healthcare Products
Innovative Science Solutions
Morristown, NJ

5:20 p.m. ADJOURN
5:45 p.m. JOINT NETWORKING RECEPTION
REGISTRATION

Please print or type one form per person; photocopy this form for additional registrants.

LAST NAME

FIRST NAME

MIDDLE NAME

NAME AS YOU WISH IT TO APPEAR ON YOUR BADGE

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WHAT STATE(S) ARE YOU LICENSED IN?

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(AREA CODE) BUSINESS TELEPHONE

FAX

E-MAIL ADDRESS

Are you attending your first Life Sciences Legal Summit? ☐ YES ☐ NO

PAYMENT INFORMATION

Registration for the entire conference is $100.

☐ CHECK (MADE PAYABLE TO THE ABA)

☐ CREDIT CARD

☐ AMERICAN EXPRESS ☐ MASTERCARD ☐ VISA

CREDIT CARD NUMBER

EXPIRATION DATE

THREE WAYS TO REGISTER

1. ONLINE: www.americanbar.org/tips
2. MAIL: 321 North Clark Street, 18th Floor, Chicago, IL 60654
3. FAX: (312) 988-6230

Registration Deadline: February 19, 2014

SIGNATURE