



MARCH 4, 2015 | GENENTECH BLDG. #83

ABA TIPS PRODUCTS LIABILITY COMMITTEE
DRUG, DEVICE, & BIOTECHNOLOGY SUBCOMMITTEE

LIFE SCIENCES LEGAL SUMMIT

611 GATEWAY BOULEVARD | SOUTH SAN FRANCISCO, CA 94080



PRESENTED BY

The ABA TIPS Products Liability Committee's
Drug, Device, & Biotechnology subcommittee

The ABA Science & Technology Law Section's
Food, Cosmetics and Nutraceuticals Committee and Biotechnology Law Committees

The ABA Litigation Section's Products Liability Committee's
Pharmaceutical, Biotech and Medical Device Subcommittee

AGENDA

This course is expected to qualify for 8 CLE credit hours for California.

8:00 a.m.

CONTINENTAL BREAKFAST

8:15 a.m. – 8:20 a.m.

WELCOME & INTRODUCTION

8:20 a.m. – 9:00 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

Scott Cunningham

Covington & Burling LLP
San Francisco, CA

Wendy Sanhai

Exponent, Inc. | Cary, NC

9:00 a.m. – 9:40 a.m.

Off Label Marketing In The Post *Caronia* World

Even after *Caronia*, the risk of criminal or civil actions alleging improper off label use promotion continues. These speakers will address the scope of the existing off-label promotion prohibitions, the battle playing out in *Solis v. Millennium*, and ways to minimize the risks of improper off label promotion claims, and effectively defend against these allegations.

Speakers

Habib Nasrullah

Wheeler Trigg O'Donnell | Denver, CO

Michelle H. Yeary

Dechert LLP | Princeton, NJ

9:40 a.m. – 10:10 a.m.

What's on the Horizon?

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

Speakers

Madeleine McDonough

Shook, Hardy & Bacon L.L.P. | Washington, D.C.

10:10 a.m. – 10:20 a.m. **BREAK**





10:20 a.m. – 11:20 a.m. **A View From The Bench:
Managing Complex Litigation In California**

This panel of California state court judges and representatives of both sides of the bar will discuss the current landscape in presiding over drug litigation in California state courts, including addressing the use and mechanics of *Daimler AG v. Bauman* jurisdictional challenges, severance, *forum non conveniens*, the application of *Sargon* in assessing expert testimony, and bellwether trial selection and management in drug cases.

Moderators

Khaldoun Baghdadi

Walkup, Melodia, Kelly, & Schoenberger
San Francisco, CA

Alicia Donahue

Shook, Hardy & Bacon | San Francisco, CA

Panel

Hon. Gail Andler

Orange County Superior Court
Orange County, CA

Hon. Richard A. Kramer

San Francisco Superior Court
San Francisco, CA

Hon. George Hernandez

Alameda Superior Court | Alameda, CA

Hon. Mary Wiss

San Francisco Superior Court
San Francisco, CA

Hon. Curtis E.A. Karnow

San Francisco Superior Court
San Francisco, CA

11:20 a.m. – 12:10 p.m. **Generic Drug Preemption and Innovator Liability Update**

These presentations will address developments over the last year in preemption for generic drug manufacturers, and innovator liability claims against brand-name manufacturers.

Speakers

Kelly Kimbrough

Bowman and Brooke LLP | Austin, TX

Steven Skikos

Skikos, Crawford, Skikos, & Joseph
San Francisco, CA

Kai Peters

Gordon & Rees | San Francisco, CA

12:10 p.m. – 1:00 p.m. **LUNCH**

1:00 p.m. – 2:00 p.m. **Managing The Corporate Counsel Relationship:
Ingredients for a Successful Attorney-Client Relationship**

Hear this prestigious corporate counsel panel cover best practices and helpful tips in maintaining and developing the attorney-client relationship.

Moderator

Holly Polglase

Hermes, Netburn, O'Connor & Spearing, P.C. | Boston, MA

Panel

Donald P. Bunnin

Senior Litigation Counsel
Allergan, Inc. | Irvine, CA

Neela A. Paykel

Assistant General Counsel
Genentech, Inc. | South San Francisco, CA

Melinda Griffith

General Counsel
CardioDX | Redwood City, CA

Jennifer Rhodes

General Counsel
Medivation, Inc. | San Francisco, CA



2:00 p.m. – 2:50 p.m.

Evaluating Evidence Used for Pharmacovigilance Signal Detection and Legal Causation Assessments

These speakers will cover the evaluation of evidence for signal detection for pharmacovigilance purposes (and possible label revisions) and for causation assessments in courts of law. This panel is designed to assist in-house counsel in advising pharmacovigilance and regulatory departments on the downstream legal significance of the description of evidence in various regulatory and company documents. It is also designed to assist outside counsel in obtaining a greater appreciation of the pharmacovigilance process within companies in meeting their regulatory obligations. Finally, this panel will discuss how companies can proactively monitor the safety and effectiveness of their products to develop systems that reduce liability claims.

Speakers

Krista L. Cosner

Senior Counsel
Medivation, Inc. | San Francisco, CA

Donald F. "Fritz" Zimmer, Jr.

King & Spalding LLP | San Francisco, CA

Steven M. Weisman

Global Healthcare Products,
Innovative Science Solutions
Morristown, NJ

2:50 p.m. – 3:20 p.m.

As Ethical as a Lawyer

There is a perception, both in the bar and on the bench, that incivility and ethical violations are on the rise. What happens when an adversary engages in unethical tactics or attack on you? How does the Court view such an attack? Through this very enlightening presentation, you will learn the tried and true tactics from the trenches to not only identify and ethically respond to this conduct, but to prevent them in the future.

Speaker

Joseph J. Ortego

Nixon Peabody LLP | New York, NY

3:20 p.m. – 3:30 p.m.

BREAK

3:30 p.m. – 4:00 p.m.

The Continued Viability of Brand Preemption Post-*Levine*

This presentation will address the extent to which impossibility preemption is still a viable argument for brand-name manufacturers.

Speakers

Randall Christian

Bowman and Brooke LLP | Austin, TX

Marc Fishman

Senior Corporate Counsel -
Head of US Litigation
Novo Nordisk | New York, NY

4:00 p.m. – 4:40 p.m.

Selecting and Trying the Bellwether Trial

These speakers will address the mechanics of bellwether trial selection, and the key considerations involved.

Speakers

Brian P. O'Donoghue

Goldman Ismail Tomaselli
Brennan & Baum LLP | Chicago, IL

Michael Healy

Sedgwick LLP | San Francisco, CA





4:40 p.m. – 5:10 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. This speaker will discuss how clinical trial agreements can be negotiated, and what potential traps may exist.

Speaker

Cristiana Spontoni

Jones Day | Brussels, Belgium

5:10 p.m. – 5:40 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 recent intellectual property developments and their effect on the life sciences industry.

Speakers

Dr. Janet M. McNicholas

Jones Day | Palo Alto, CA

Dr. Diane Wilcock

Senior Director of Intellectual Property
XOMA Ltd. | Berkeley, CA

5:40 p.m.

ADJOURN

5:40 p.m.

ON-SITE 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

FIRM/COMPANY

WHAT STATE(S) ARE YOU LICENSED IN?

ADDRESS

CITY

STATE

ZIP

(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 \$150.

CHECK (MADE PAYABLE TO THE ABA)

CREDIT CARD

AMERICAN EXPRESS

MASTERCARD

VISA

CREDIT CARD NUMBER

EXPIRATION DATE

SIGNATURE

THREE WAYS TO REGISTER

1. ONLINE: www.americanbar.org/tips

2. MAIL: **Life Sciences Legal Summit**
American Bar Associates
Attn: Service Center-Meeting/Event Registrations Department
321 North Clark Street, Floor 16
Chicago, IL 60654

3. FAX: (312) 988-5850

