



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](http://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

