Genentech
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THIRD ANNUAL

LIFE SCIENCES LEGAL SUMMIT

611 GATEWAY BOULEVARD | SOUTH SAN FRANCISCO, CA

SEPTEMBER 21, 2016 | GENENTECH BLDG. #83

SPONSORED BY

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

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TORT TRIAL INSURANCE

AMERICAN BAR ASSOCIATION
Section of Litigation

ABA SECTION OF SCIENCE & TECHNOLOGY LAW

AGENDA

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

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

8:30 a.m. – 8:40 a.m. **WELCOME & INTRODUCTION**

Michael Listgarten, Esq., *Event Co Chair, Senior Associate General Counsel, Senior Director and Co-Lead, Healthcare Law Group, Genentech, Inc. Inc, South San Francisco, CA*

8:40 a.m. – 9:00 a.m. **OPENING REMARKS FROM EVENT CO CHAIR ON THE FUTURE OF LIFE SCIENCES LITIGATION ISSUES**

Madeleine M. McDonough, Esq., *Event Co-Chair, Shook, Hardy & Bacon L.L.P., Washington D.C.*

9:00 a.m. – 9:40 a.m. **UNDER THE WATCHFUL EYE OF THE FDA: WHAT DO FDA WARNING LETTERS TELL US?**

The FDA provides oversight in the life sciences industry through inspections and audits of manufacturers, vendors/suppliers, and others to ensure compliance with quality systems. These quality systems provide a framework for manufacturers to achieve quality requirements for designing, manufacturing, packaging, labeling, storing, installing, and servicing of their products. This presentation will provide a brief overview of quality system management and FDA inspections, as well as a retrospective analysis of FDA inspections and warning letters.

Speakers:

John Fuson, Esq., *Crowell & Moring L.L.P., Washington D.C.*

Kevin L. Ong, Ph.D., *Exponent, Inc., Philadelphia, PA*

9:40 a.m. – 10:10 a.m. **THE KEY DECISIONS AFFECTING DRUG AND DEVICE LITIGATION IN THE LAST YEAR**

The last 12 months have seen a number of cases with significant implications to pharmaceutical and medical device litigation. This speaker will provide an overview of the key decisions affecting drug and device litigation.

SpeakerS:

Stephen J. McConnell, Esq., *Reed Smith L.L.P., Philadelphia, PA*

Erin M. Bosman, Esq., *Morrison & Forester, L.L.P. , San Diego, PA*

10:10 a.m. – 10:20 a.m. **BREAK**

10:20 a.m. – 11:00 a.m. **OFF LABEL MARKETING AND FREE SPEECH IN THE POST *CARONIA* AND *AMARIN* WORLD**

As courts increasingly recognize that truthful off-label promotion is protected free speech, these speakers will address the evolving regulatory and litigation arena.

Speakers:

Stephen C. Matthews, Esq., *Porzio, Bromberg & Newman, P.C., Morristown, NJ*

Habib Nasrullah, Esq., *Wheeler Trigg O'Donnell L.L.P., Denver, CO*

11:00 a.m. – 12:00 p.m.

A VIEW FROM THE BENCH AND BAR: COMPLEX DRUG AND DEVICE LITIGATION IN CALIFORNIA

This panel of California judges and representatives of both sides of the bar will discuss the current landscape of drug and device litigation in California courts.

Moderators:

Khaldoun Baghdadi, Esq., *Walkup, Melodia, Kelly, & Schoenberger, San Francisco, CA*

Michael Healy, Esq., *Sedgwick L.L.P., San Francisco, CA*

Panel:

Hon. Gail Andler, *Orange County Superior Court, Orange County, CA*

Hon. George Hernandez, *Alameda Superior Court, Alameda, CA*

Hon. Laurel Beeler, *USDC Northern District of California, San Francisco, CA*

Hon Elihu Berle, *Los Angeles Superior Court, Los Angeles, CA*

12:00 p.m. – 12:50 p.m.

NETWORKING LUNCH – PROVIDED ON SITE

12:50 p.m. – 1:50 p.m.

INSIDE VIEW: LEGAL AND ETHICAL CONSIDERATIONS FOR IN-HOUSE COUNSEL

Corporate counsel life can present its own set of challenges. This distinguished panel will address some the challenging issues faced by corporate counsel when retaining and managing outside counsel and when overseeing corporate responsibility and compliance issues as well as when dealing with complex litigation.

Moderator:

Sean Wajert, Esq., *Shook, Hardy & Bacon L.L.P., Philadelphia, CA*

Panel:

Donald P. Bunnin, Esq., *Senior Litigation Counsel, Allergan, Inc. Irvine, CA*

Jennifer Rhodes, Esq., *General Counsel, Adamas Pharmaceuticals, Inc., San Francisco, CA*

Christopher P. Gramling, Esq., *Assistant General Counsel, Eli Lilly and Company, Indianapolis, IN*

Edward O. Gramling, Esq., *Senior Corporate Counsel, Pfizer, New York, NY*

David Wildman, Esq., *Senior Counsel, Genentech, Inc., South San Francisco, CA*

1:50 p.m. – 2:20 p.m.

INNOVATOR LIABILITY UPDATE

This presentation will address developments affecting innovator liability claims against current and former brand manufacturers including the potential impact of *T.H. v. Novartis.*

Speaker:

Michael Imbroscio, Esq., *Covington & Burling L.L.P., Washington D.C.*

2:20 p.m. – 3:00 p.m.

THE RENEWED VIABILITY OF BRAND PREEMPTION

Following *Wyeth v. Levine*, courts have required brand manufacturers arguing preemption to show "clear evidence" that the FDA would have rejected the label change at issue in the litigation. This presentation will provide guidance on the purported "clear evidence" standard and discuss recent decisions addressing brand preemption.

Speakers:

Kelly Kimbrough, Esq., *Bowman and Brooke L.L.P., Austin, TX*

Rachel Abrams, Esq., *Levin Simes L.L.P., San Francisco, CA*

3:00 p.m. – 3:10 p.m.

BREAK

3:10 p.m. – 3:50 p.m.

PRETRIAL STRATEGIES IN HANDLING DRUG AND DEVICE MASS TORTS

These speakers will address techniques and strategies in handling mass torts well before trial.

Speakers:

Paul E. Boehm, Esq., *Williams & Connolly L.L.P., Washington, D.C.*

Brian P. O'Donoghue, Esq., *Goldman Ismail Tomaselli, Brennan & Baum L.L.P., Chicago, IL*

3:50 p.m. – 4:20 p.m.

TRYING THE BELLWETHER/MASS TORT CASE IN THE MODERN ERA

When mass tort cases go to trial, whether as bellwethers or otherwise, the first series of trials can have profound implications on the entire litigation. This leading trial lawyer will provide tips on trying these high-stakes cases, and effectively communicating with the modern juror in these science-intensive trials.

Speaker:

Robert T. Adams, Esq., *Shook, Hardy & Bacon L.L.P., Kansas City, MO*

4:20 p.m. – 5:00 p.m.

TRENDS IN CLINICAL TRIALS AND LIABILITY ENFORCEMENT ACTIONS

Clinical research is the lifeblood of the life sciences industry, but invariably presents regulatory and litigation exposure. These speakers will provide an overview of the risks and tips on how to minimize them.

Speakers:

Dr. Prerna Minon, *Associate Director, Regulatory Affairs NGM Biopharmaceuticals, South San Francisco, CA*

Maureen Bennett, Esq., *Jones Day, Boston, MA*

5:00 p.m. – 5:40 p.m.

INTELLECTUAL PROPERTY UPDATE: HOT BUTTON ISSUES 2016

These speakers will present an overview of recent intellectual property developments and their effect on the life sciences industry.

Speakers:

Dr. Danielle M. Paqualone, Esq., *Assistant General Counsel, Genentech, Inc., South San Francisco, CA*

Dr. Janet M. McNicholas, Esq., *Jones Day, Palo Alto, CA*

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

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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 $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
Meeting Code: IL1609LIFE
321 North Clark Street
Floor 16
Chicago, IL 60654

3. FAX: **(312) 988-5850**

CLE INFORMATION

The ABA directly applies for and ordinarily receives CLE credit for ABA programs in AK, AL, AR, AZ, CA, CO, DE, GA, GU, HI, IA, IL, IN, KS, KY, LA, MN, MS, MO, MT, NH, NM, NV, NY, NC, ND, OH, OK, OR, PA, PR, SC, TN, TX, UT, VT, VA, VI, WA, WI, and WV. These states sometimes do not approve a program for credit before the program occurs. This courses is expected to qualify for 7.50 CLE credit hours (including 1.0 ethics hours) in 60-minute states, and 9 credit hours (including 1.20 ethics hours) in 50-minute states. This transitional program is approved for both newly admitted and experienced attorneys in NY. Attorneys may be eligible to receive CLE credit through reciprocity or attorney self-submission in other states. For more information about CLE accreditation in your state, visit **http://www.americanbar.org/groups/tort_trial_insurance_practice.html** or contact Donald Quarles at donald.quarles@americanbar.org or 312.988.5708.

SCHOLARSHIPS AVAILABLE!

ATTENTION TIPS MEMBERS: Scholarships are available for all Section activities, courtesy of the TIPS Scholarship Fund. The Fund, established with the International Risk Management Institute ("IRMI") and supported by subscriptions to the IRMI CGL Reporter, is intended to increase membership involvement in TIPS activities among minorities, solo and small firm practitioners, plaintiffs, government attorneys, women, law students, and young lawyers byproviding financial support to those who would otherwise be unable to participate. To request an application or receive additional information, visit **www.americanbar.org/groups/tort-trial_insurance-practice/about_us/scholarship_fund.html** or contact Daniel Chavez at 312-988-5561.

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