AMERICAN BAR ASSOCIATION

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TORT TRIAL & INSURANCE PRACTICE

FIFTH ANNUAL

LIFE SCIENCES LEGAL SUMMIT

WEDNESDAY, SEPTEMBER 26, 2018

GENENTECH BLDG. #83 | 611 GATEWAY BOULEVARD | SOUTH SAN FRANCISCO, CA

SPONSORED BY

The ABA TIPS Products Liability Committee

The ABA TIPS Pharmaceutical, Medical Device and Biosciences Committee

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

AGENDA

8:00 a.m. – 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., South San Francisco, CA

Amir Nassihi, Esq. | Event Co Chair, Chair Elect ABA TIPS Pharmaceutical, Medical Device and Biosciences Committee

8:40 a.m. – 10:00 a.m.

RECENT ENFORCEMENT TRENDS IN LIFE SCIENCES- UNDERSTANDING AREAS OF CONCERN FROM ADVERTISING/ PROMOTION TO COMPETITION AND GMP ENFORCEMENT

The last year has seen a flurry of regulatory and enforcement activity. This panel will examine the FTC and FDA's new leadership, what we're seeing with antitrust and advertising/marketing law enforcement in the life sciences field, FDA and US DOJ trends and activity in relation to investigations and enforcement action, with a particular focus on Good Manufacturing Practice Regulation and alleged violations, and potential FCA litigation.

Moderator:

Stephen C. Matthews, Esq. | DLA Piper, Short Hills, NJ

Speakers:

Ralph Caccia, Esq. | Wiley Rein, Washington D.C.

Sonali P. Gunawardhana, Esq. | Shook, Hardy & Bacon, Washington, D.C.

Steve Vieux Esq. | Shook, Hardy & Bacon, San Francisco, CA

10:00 a.m. – 10:30 a.m.

WHAT'S ON THE HORIZON? THE EVOLVING FDA REGULATION OF DIGITAL HEALTH PRODUCTS

From digital medicines to mobile medical applications and wearable health technology to advanced analytics and AI, digital products are a growing portion of the medical device economy. Recent regulatory developments that have impacted the digital health sector will be discussed, including FDA's current efforts to encourage digital health product development, such as the development of a novel regulatory paradigm for software-based medical products.

Speakers:

Ian M. Pearson, Esq. | Jones Day, San Francisco, CA

Soleil Boughton, Esq. | Corporate Counsel, Google, Mountain View, CA

10:30 a.m. – 10:40 a.m.

BREAK

AGENDA

10:40 a.m. – 11:10 a.m.

NAVIGATING CLINICAL, REGULATORY, AND REIMBURSEMENT RISKS – UPDATE ON COMMERCIALIZATION STRATEGIES

Development of innovative medicines involves clinical trial, regulatory, and reimbursement risks and requires new strategies to maximize value to patients. The speakers will provide tips for navigating the risks, including navigating through new and evolving regulatory pathways, and increasing the opportunities for successful product commercialization by life sciences companies.

Speakers:

Claire Castles, Esq. | Jones Day, Los Angeles, CA
Dr. Jill E. Sackman | Exponent, Detroit, MI

11:10 a.m. – 12:00 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 of the 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:

Holly Polglase, Esq. | Immediate Past Chair, ABA Tort Trial & Insurance Practice Section

Panel:

Christopher P. Gramling, Esq. | Assistant General Counsel, Eli Lilly and Company, Indianapolis, IN
Edward O. Gramling, Esq. | Senior Corporate Counsel, Pfizer, New York
Jacquie Haggarty, Esq. | Deputy General Counsel, 23andMe, Mountain View, CA
Neela Paykel, Esq. | Vice President, Head of Legal, Proteus Digital Health, Redwood City, CA

12:00 p.m. – 1:00 p.m.

LUNCH

1:00 p.m. – 2:10 p.m.

A VIEW FROM THE BENCH: BEST PRACTICES IN MANAGING COMPLEX LITIGATION

This panel of California federal and state court judges, moderated by representatives of both sides of the bar, will discuss best practices in effectively and efficiently managing complex litigation.

Co-Moderators:

Khaldoun Baghdadi, Esq. | Walkup, Melodia, Kelly, & Schoenberger, San Francisco, CA
Amir Nassihi Esq. | Event Co Chair, Chair Elect ABA TIPS Pharmaceutical, Medical Device and Biosciences Committee

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Panel:
Honorable James Donato | Northern District of California, San Francisco, CA
Honorable William F. Highberger | Los Angeles Superior Court, Los Angeles, CA
Honorable Ioana Petrou | Alameda Superior Court, Alameda, CA
Honorable Mary Wiss | San Francisco Superior Court, San Francisco, CA

2:10 p.m. – 2:50 p.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 in areas such as the interplay between first amendment defenses and off label marketing claims, brand preemption, innovator liability, and personal jurisdiction. These speakers will provide an overview of these and other key decisions affecting drug and device litigation.

Speakers:
Randall L. Christian, Esq. | Bowman and Brooke, Austin, TX
Kacy Wiggum, Esq. | Senior Attorney, Novo Nordisk, Plainsboro, NJ

2:50 p.m. – 3:00 p.m.

BREAK

3:00 p.m. – 3:40 p.m.

NAVIGATING SCIENTIFIC ISSUES IN MASS TORTS

The last few years has seen a sharp uptick in pharmaceutical mass torts. This has increased the importance of Science Days to effectively educate the court, increased consideration of Lone Pine type orders, and development of case management techniques to address general and specific causation across batches of cases. These speakers will provide an overview on these issues and cover best practices.

Speakers:
Martin Healy, Esq. | Porzio, Bromberg & Newman, P.C., Morristown, NJ
Mark Crawford, Esq. | Skikos, Crawford, Skikos & Joseph, San Francisco, CA

3:40 p.m. – 4:10 p.m.

RECENT DEVELOPMENTS IN CLASS ACTION LITIGATION

Class actions remain among the most daunting civil litigation threats faced by product manufacturers. This speaker will provide an update on recent class action trends.

Speakers:
Andrew Trask, Esq. | McGuire Woods, Los Angeles, CA

AGENDA

4:10 p.m. – 4:40 p.m.

THE CHANGING SHAPE OF THE THIRD PARTY LITIGATION FUNDING BATTLEGROUND

The role of undisclosed third parties in litigation as lead generators, litigation funders, or in directing publicity efforts to shape public opinion is under increasing scrutiny. These speakers will examine the case for and against disclosure of third party involvement, associated strategies, and the ethical implications of undisclosed nonparty involvement.

Speakers:

Mary Novacheck, Esq. | Bowman and Brooke, Minneapolis, MN
Steven Skikos, Esq. | Skikos, Crawford, Skikos & Joseph, San Francisco, CA

4:40 p.m. – 5:20 p.m.

INTELLECTUAL PROPERTY UPDATE 2018 – DO PATENTS STILL MATTER?

Intellectual property has been essential to the development and commercialization of innovative medicines by life science companies. The panel will discuss recent IP developments and their effect on the life sciences industry, including the role of patents in the discovery and development of new life-saving and life-transforming medicines.

Speakers:

Janet M. McNicholas, Ph.D., Esq. | Jones Day, Palo Alto, CA
Danielle M. Pasqualone, Ph.D., Esq. | Five Prime Therapeutics, South San Francisco, CA
Stephanie Yonker, Ph.D., Esq. | Alector LLC, South San Francisco, CA
Susan A. Abrahamson, Ph.D., Esq. | Sangamo Therapeutics, Richmond, CA

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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 _____ Z I P _____

(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: IL1709LIFE
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, CT, DE, GA, GU, HI, IA, IL, IN, KS, KY, LA, ME, MN, MS, MO, MP, MT, NH, NJ, NM, NV, NY, NC, ND, OH, OK, OR, PA, 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 course is expected to qualify for 7.50 CLE credit hours in 60-minute states, including 0.83 credits of ethics. 9.00 CLE credit hours in 50-minute states, including 1.00 CLE ethics specialty credits. 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 (**https://ambar.org/tips**) Or contact Juel Jones at 312-988-5597.

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 by providing 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 Theresa Livingston at 312-988-6155.