

American Society for Pharmacy Law

November 6 - 9, 2014

Hyatt Regency Indian Wells Resort & Spa - Indian Wells, California

Thursday, November 6, 2014

8:30 am – 5:00 pm **ASPL Board Meeting**

3:00 pm – 5:00 pm **Registration Open**

5:30 pm – 7:00 pm **ASPL Opening Reception**

Friday, November 7, 2014

7:00 am – 5:00 pm **Registration Open**

7:00 am – 8:00 am **Breakfast**

8:00 am – 8:15 am **Welcome**

8:15 am – 9:45 am **Legislative and Regulatory Update**

Federal and state legislative and regulatory activity that impact payment for medications, professional services, and government initiatives that impact the quality and safety of medications constantly evolve and legal professionals in pharmacy must understand the impact of these changes to pharmacists and pharmacies. This session will provide an update on the latest developments in federal and state regulations impacting pharmacy and pharmacists including compounding, Medicare Part D, health care reform, controlled substances, and provider status.

Mary Jo Carden, RPh, JD, Academy of Managed Care Pharmacy
(1.5 credit hours)

9:45 am – 10:00 am **Break**

10:00 am – 11:00 am **Update: Mitigating False Claims Act and Consumer Protection Exposure for Retail Pharmacies**

Retail pharmacies' vulnerability to whistleblower cases under federal and state False Claims Acts has grown as government reimbursement expands and costs to government payors increase. At the same time, state consumer protection agencies are becoming more active in investigating pharmacies and threatening injunctions and penalties to enforce their regulations. This interactive session will review recent enforcement trends for retail, mail order and specialty pharmacies.

Barbara Rowland, Principal; John Joseph, Principal, Post & Schell, PC
(1 credit hour)

11:00 am – 12:00 pm **The Legal Implications of Pharmacist Provider Status: the Past, Present, and Future of a Transformative Movement**

This presentation will explore the quest for pharmacist provider status by outlining the history of the movement, current legislative and lobbying efforts, and the potential industry-wide impact and significance of provider designation. In addition to providing up-to-date information on federal and state legal reforms, this session will explore how the practice of pharmacy may be transformed through greater regulatory scrutiny, expanded credentialing

requirements, and increased patient-related demands.

John S. Linehan, Ober/Kaler (1 credit hour)

12:00 pm – 1:00 pm **Lunch**

1:00 pm – 3:00 pm **Case Law Update**

Once again, there have been significant court decisions affecting many areas of pharmacy and the pharmaceutical industry. This presentation will summarize cases involving pharmacy board decisions, pharmacists' liability, product liability, drug product labeling, the Federal False Claims Act, anti-kickback claims, and more.

Roger Morris, RPh, JD, Quarles & Brady, LLP; William Stilling, RPh, MS, JD, Parsons Behle & Latimer (2 credit hours)

3:00 pm – 3:15 pm **Break**

3:15 pm – 4:15 pm **What's Next?: The Ever Changing Landscape of Pharmacy Compounding**

This presentation will shed light on the expected impact on pharmacy compounding from the Drug Quality and Security Act on pharmacies and pharmacists. Attendees will gain insight on the history and foundation of pharmacy compounding, highlighting past case law and FDA guidance and focusing on recent legislative and FDA actions. The presentation will focus on both the expected challenges and the likely opportunities for pharmacists presented by the DQSA as it is implemented.

Frank Palumbo, PhD, Esq, University of Maryland School of Pharmacy Center on Drugs & Public Policy; Lee Rosebush, PharmD, RPh, JD, MBA, MS, BakerHostetler (1 credit hour)

4:15 pm – 5:15 pm **Maintaining an Effective Controlled Substance Compliance Program**

This session will provide strategies and tools for companies to use in maintaining an effective program to comply with federal and state requirements on the receipt, storing, distribution and dispensing of controlled substances. It also will emphasize areas such as where investigators/inspectors are known to focus their inspections, how to be prepared for these inquiries, when and if to authorize employee interviews, the importance of developing techniques to "audit the investigator" and how to "own your data" to ensure ongoing compliance and successful audits.

John A. Gilbert, Jr, JD, Hyman, Phelps & McNamara, PC
(1 credit hour)

6:30 pm – 8:30 pm **Reception**

Afternoon of Golf

Are you interested in playing a round of golf on Saturday? We would play at the hotel golf course (if available) or at a local golf course starting at 12:00 noon. Format (e.g., scramble) and cost will be dependent upon the number of players, but a fair estimate is \$130. *Please respond to Aaron Moore by Sept. 5, 2014 if you intend to play and/or have any questions at amoore@gdldlaw.com or 410-783-4994.*

Register Today at www.aspl.org

Saturday, November 8, 2014

7:00 am – 12:00 pm **Registration Open**

7:00 am – 8:00 am **Breakfast**

8:00 am – 10:00 am **Ethics: A Case-Based Approach**

This session will study legal and pharmacy ethics as they relate to ethical decision-making both for the pharmacist and the lawyer. The program will explore legal and pharmacy ethics by interacting with the lawyers and pharmacists in the audience while examining decisions and incidents, real and hypothetical, in both professions.

Ken Baker, BS Pharm JD, Renaud Cook Drury Mesaros, PA; Bruce D. White, DO, JD, Alden March Bioethics Institute (2 credit hours)

10:00 am – 10:15 am **Break**

10:15 am – 11:15 am **Implications of the Drug Quality and Security Act on Track and Trace Requirements**

On November 27, 2013, President Obama signed into law the Drug Quality and Security Act (H.R. 3204). Title II of the Act, the Drug Supply Chain Security Act, establishes a national system for tracing pharmaceutical products through the supply chain and sets national licensing standards for wholesale distributors and third-party logistics providers. This Act will change the way prescription drugs are distributed in the United States over the next 10 years. This session will discuss these changes and their impact on stakeholders.

Martha Russell, Cardinal Health; Susan Pilch, JD, National Community Pharmacists Association (1 credit hour)

11:15 am – 12:15 pm **What Should CIA's Be Telling Me? Using Recent Corporate Integrity Agreements to Inform and Assess Your Compliance Program's Effectiveness**

Corporate integrity agreements ("CIAs") are a common feature of health care fraud settlements and they offer important lessons about expectations for effective compliance programs for health care providers. CIAs shed light on the government's thinking on industry best practices, and help organizations to identify risk areas and to benchmark their own compliance practices. This presentation will discuss trends in recent CIAs and what they mean for pharmacies and related organizations not under a CIA themselves.

Deborah Gersh, Partner; Brett Friedman, Partner, Ropes & Gray (1 credit hour)

2:00 pm – 4:30 pm **Pharmacy Law Educators**

Join other pharmacy law educators to share information and materials to assist with course development and student assessment.

Sunday, November 9, 2014

7:00 am – 12:00 pm **Registration Open**

7:00 am – 8:00 am **Breakfast**

8:00 am – 9:00 am **Pharmacy and the Continuum of Lethal Injection**

Lethal injection drug shortages in the US are disrupting the capital punishment process. This program reviews clinical, legal, and ethical implications of lethal injections, including: (1) scientific/

clinical origins; (2) key jurisprudential cases; (3) supply chain disruption; and (4) fundamental ethical principles involved. Dilemmas in supply chain disruption are an opportunity for the professions of pharmacy and law to reflect on the objectives of lethal injection in civilized society.

James Ruble, PharmD, JD, University of Utah College of Pharmacy (1 credit hour)

9:00 am – 10:00 am **Use of Technology for Telepharmacy and Remote Dispensing**

This interactive session will provide a comprehensive overview of remote dispensing and telepharmacy regulations from a patient, pharmacy, physician, healthcare facility perspective as well as an overview of technology advancements in the field of remote pharmacy services. The session also will focus on a variety of related federal and state regulations as well as operational issues associated with the technology. Practical operational and regulatory considerations applicable when developing remote dispensing/telepharmacy regulation, particularly concerning the integration of the technology into an existing IT infrastructure will be discussed.

Loreto Grimaldi, JD, Medavail Technologies; Michael Simko, RPh, Walgreens (1 credit hour)

10:00 am – 10:15 am **Break**

10:15 am – 11:45 am **Marijuana: The Evolving Issues**

This program will summarize the state of state marijuana laws, legal implications of real-life clinical and business issues that arise in all states as a result of the conflict between federal and state laws, and ethical considerations for attorneys who advise clients and pharmacists who participate in a marijuana business.

Laura Carpenter, RPh, JD, LLM, Carpenter Law Firm PC; William Stilling, RPh, MS, JD, Parsons Behle & Latimer (1 credit hour)

Accommodations:

A block of rooms has been reserved for the ASPL Seminar at the Hyatt Regency Indian Wells Resort & Spa, Indian Wells, California. The resort is located at 44600 Indian Wells Lane, Indian Wells, California 92210.

Room Rate is \$169 plus 11.25% tax. Call 1-888-421-1442 to make your reservation. Be sure to identify yourself with the ASPL meeting to receive this special rate. The hotel reservation cut-off date is October 14, 2014.

When you make your room reservation, you will need to guarantee the room with a credit card. The cancellation of a guaranteed reservation must be received 72 hours prior to arrival to avoid a charge of one night's room and tax. *Space is limited so make your reservations today!*

Travel:

Air Transportation: The Hyatt Regency Indian Hills Resort and Spa is conveniently located 15 miles from Palm Springs International Airport.

Ground Transportation:

Rental Car: Eight (8) National chains service the Palm Springs International Airport: Alamo, Avis, Budget, Dollar, Enterprise, Hertz, National and Thrifty.

Taxi: Taxis are available curbside, outside baggage claim. Approximate cost is \$60 (plus gratuity) each way.

Shuttle: Service First Transportation, 760-272-0960. Vehicles accommodate 1-6 passengers in courteous and clean comfort. Fee from Palm Springs International Airport is \$80 (plus gratuity) each way.