2017 ASPL Fall Meeting

Hotel Valley Ho - Scottsdale, AZ

November 2-5, 2017

Developments in Pharmacy Law Seminar XXVIII

Thursday, November 2, 2017

3:00 p.m. to 5:00 p.m. **Registration Open**

5:30 p.m. to 7:00 p.m. **ASPL Opening Reception**

Friday, November 3, 2017

7:00 a.m. to 5:00 p.m. **Registration Open**

7:00 a.m. to 8:00 a.m. **Breakfast**

8:00 a.m. to 8:30 a.m. **Opening Welcome, Installation of 2018 Officers and Board of Directors**

8:30 a.m. to 9:30 a.m.

What's Now in the Mix? Compounding Four Years after NECC and the DQSA

0071-9999-17-018-L03-P (1.0 credit hours, 0.10 CEU*)

This session will briefly address the state of compounding since the passage of the DQSA. The session also will provide an overview of the current federal regulation of compounding, touching on issues involving inspections, recalls, administrative actions, and criminal and civil actions involving pharmacies and outsourcing facilities. It will also address looming issues for compounders including the new "prescription requirement," anticipatory compounding, draft guidance addressing "essentially copies," the state of the draft FDA/state MOU, and importantly, the effect, if any, of the Trump administration's executive actions on FDA's enforcement activities under 503A and 503B. Lastly, Ms. Palmer will discuss FDA's bulk substances positive and negative lists and the quarterly meetings of the Pharmacy Compounding, Advisory Committee addressing the bullks list.

Karla Palmer, JD, Hyman Phelps & McNamara, PC

9:30 a.m. to 10:30 a.m.

Goldilocks: Applying the Healthcare and IRB Law and Ethical Policy to Big Data Companies for Ethical Use--Too Much, Too Little, or Just Right?

0071-9999-17-019-L03-P (1.0 credit hours, 0.10 CEU*)

In the healthcare industry, regulations and historical practice, (both positive and negative) have shaped the foundations of ethical collection, analysis and use of sensitive data. However, in the era of big data and companies beyond healthcare, is egregious history destined to repeat itself when it comes to use of private data and information, or can we prevent damage by providing and applying the healthcare framework to big data companies? We will explore this host of potential ethical dilemmas in this session.

Erin Albert, RPh, MBA, PharmD, JD, PAHM, Myers and Stauffer, Pharmacy Podcast; Valita Fredland, MA, JD, Indiana University

10:30 a.m. to 10:45 a.m. **Break**

10:45 a.m. to 11:45 a.m.

PBM Contracting, Reimbursement And Auditing Issues

0071-9999-17-020-L03-P (1.0 credit hours, 0.10 CEU*)

Most states have enacted legislation that impact contracts between pharmacies and PBMs, such as limits on audits, any willing pharmacy laws, and reimbursement standards including limits on Maximum Allowable Cost (MAC) lists. At the federal level, legal standards address pharmacy networks and reimbursement in the Medicare, Medicaid and Tricare programs. Contractual relations may undergo even greater transformation in the near future as a result of legislative and regulatory proposals related to healthcare reform. Meanwhile, PBMs recently succeeded in litigation challenging a major state PBM law, which may be a harbinger of future efforts to limit or eliminate states' PBM standards. Pharmacies are also involved in litigation against PBMs, challenging network access limits, reimbursement policies and other PBM contracting practices. In this session two presenters will offer the pharmacy and PBM perspectives on contracting issues and the future of pharmacy-PBM relations.

Don Bell, JD, National Association of Chain Drug Stores; Barbara Levy, JD, PCMA

11:45 a.m. to 12:30 p.m. **Lunch**

12:30 p.m. to 12:45 p.m. **Annual Meeting**

1:05 p.m. to 2:05 p.m. **CONCURRENT SESSIONS**

The Benefits and Legal Implications of Community-based Telepharmacy

0071-9999-17-026-L03-P (1.0 credit hours, 0.10 CEU*)

Telepharmacy, the delivery of pharmacist supervised products and professional services via telecommunications, is revolutionizing the way pharmacists operate, dispense pharmaceuticals and take care of patients. Discussions on telepharmacy are growing, as is the urgency to implement remote-dispensing solutions across the United States. But what is community-based or outpatient telepharmacy? How can we use telepharmacy to benefit patients in a variety of settings? What does the regulatory environment look like? How can you go about creating or changing the telepharmacy regulations in your state? Join us for an informative discussion about the evolution of telepharmacy, the current regulatory environment and how it's helping pharmacists improve patient outcomes in underserved areas. We'll dive into the details of the past, present, and future of

telepharmacy, including the different types, how the patient benefits, use cases, the regulatory environment, opportunities to improve care and what states are currently doing with rules surrounding the practice of remote dispensing.
Adam Chesler, PharmD, Cardinal Health; Michael Moné, BSPharm, JD, FAPhA, Cardinal Health

The DEA Is Here to Stay: Recent Enforcement Actions and Using Your Own Data to Protect Against Diversion

0071-9999-17-022-L03-P (1.0 credit hours, 0.10 CEU*)

In 2016 and 2107, the Drug Enforcement Administration (DEA) continued its industry-wide enforcement actions against wholesalers and large pharmacy companies that distribute and dispense controlled substances regulated under the Controlled Substances Act. Since 2013, over $300 million in fines and penalties under the Controlled Substances Act were recovered, including record-setting settlements with major retailers and distributors. In this session, we will cover recent federal enforcement trends of the Department of Justice and DEA and the challenges presented to pharmacies and wholesalers. We will discuss both typical and evolving red flag metrics targeted by DEA and how metrics may reflect patterns of ordering, prescribing, and dispensing that can be aligned with either diversion or legitimate business practices and, in some instances, both. Finally, we will discuss actions that pharmacies and wholesalers can take using their own data and compliance practices to proactively identify and address risk.
Larry Cote, JD, Quarles & Brady LLP; Crystal Pike, MBA, Analysis Group, Inc.; Barbara Rowland, JD, Post & Schell, P.C.

2:10 p.m. to 3:10 p.m. CONCURRENT SESSIONS

The Anti-Kickback Statute – Pitfalls and Safe Harbors

0071-9999-17-023-L03-P (1.0 credit hours, 0.10 CEU*)

The federal Anti-Kickback Statute (AKS) poses significant legal risks for pharmacies. The AKS broadly prohibits offering, paying, or receiving anything of value in exchange for the referral of federal health care program patients or business. Violations of the AKS can result in significant civil penalties, exclusion from participation in federal health programs, criminal fines, and imprisonment. AKS violations can also trigger liability under the False Claims Act. Because of its scope, the AKS can implicate a variety of pharmacy operations from supplier agreements to consumer marketing programs. This program will provide an overview of the current AKS regulatory scheme, including prohibited conduct and recently expanded safe harbors. The program will also review enforcement actions and discuss how pharmacies can identify potentially problematic programs.
Shannon Cox, JD; Stephen Cummings, JD; Meredith Young, JD, King and Spalding LLP

Retaliation Alleging Defamation by Pain Mill Doctors

0071-9999-17-024-L03-P (1.0 credit hours, 0.10 CEU*)

In response to the more stringent constraints imposed by the DEA and regulatory requirements of pharmacy, a wellspring of litigation alleging defamation by "pill mill" doctors against pharmacists and retail pharmacies refusing to fill their prescriptions has developed. This presentation is designed to acquaint the group with the legal ramifications arising from an allegation of defamation/tortious interference in a civil suit as well as a pharmacist's standard of care when interacting with customers. A focus of this presentation will discuss the landmark holding in the LeFrock vs Walgreens case wherein the Federal District Court ruled that a qualified privilege exists between a pharmacist and their customer. This discussion will include the extent of this privilege and its ramifications related to consultation between pharmacists and their customers. Next will be discussed the topic of appropriate statements and, as importantly, inappropriate statements by pharmacists related to the non-filling of a prescription due to issues of DEA noncompliance. Examples will be provided from real case experience.
Arthur Laplante, Esq, Hinshaw and Culbertson; Martin Stern, JD, Hinshaw and Culberton; Bret Stacey, JD, Walgreen Co.

3:10 p.m. to 3:25 p.m. BREAK

3:25 p.m. to 4:25 p.m. CONCURRENT SESSIONS

Everything's Coming Up Roses, But Watch for the Thorns!: Expanding Pharmacist Scope of Practice and Related Legal Issues

0071-9999-17-025-L03-P (1.0 credit hours, 0.10 CEU*)

Pharmacists are no longer just dispensers of prescriptions drugs. Starting with flu shots, over the past couple of decades, pharmacist services gradually have been expanding to include many other activities to better serve patients. Now, pharmacists provide not only flu shots but several other services as well. However, with these new opportunities come new or expanded legal responsibilities and risks for pharmacists and pharmacies. After starting with a brief history of the expansion of pharmacist scope of practice, the presentation will discuss the current reach of pharmacists' expanded practice and where else it may lead, as well as potential roadblocks. It will then proceed to give a lay of the land regarding state and federal laws impacting this evolving area, moving on to identify potential future legal changes impacting the expanding practice of pharmacy. Lastly, the potential risk areas related to expanded scope of practice will be examined and illuminated by examples.
Mary Ellen Kleiman, JD, CAE, National Association of Chain Drug Stores

Prescription Drug Monitoring Programs - Solution to the Opiate Epidemic?

0071-9999-17-021-L03-P (1.0 credit hours, 0.10 CEU*)

In this era of ever-burgeoning information technology, Prescription Monitoring Programs (PMPs) continue to flourish and expand as a valuable tool to: 1) effectively regulate the dispensing of controlled substances; 2) reduce abuse of prescription opioids; 3) promote access for legitimate medical needs; and 4) provide timely information to support a prescriber's clinical judgment while maintaining the privacy of protected health information. PMPs have rapidly grown across the country, with 49 states having implemented PMPs in some form, but many regulatory and technological differences remain, creating a barrier to effective data sharing by clinicians in different jurisdictions.

The presenters will discuss the dilemmas that PMPs present, including the various regulatory issues surrounding their creation and implementation; limiting access to authorized users;

administrating the programs on a multi-state level; privacy concerns; the current lack of clarity for the practitioner in accessing the data; additional professional time commitments by prescribers and dispensers; and the potential for under-prescribing for patients with genuine medical needs while providing appropriate access and regulating controlled substances for legitimate medical needs.

The presenters will address possible approaches to coordinating PMPs across state lines, showing how PMPs can be effective for curtailing inappropriate dispensing within the state, amongst states and potentially on a national scale.

Joseph Bova, MS RPh, Long Island University (LIU Pharmacy); Frederick Fern, RPh, Esq., Harris Beach PLLC; Marina Plotkin, RPh, Esq., Harris Beach PLLC

4:30 p.m. to 5:30 p.m.

The Controversy over Prescription Drug Pricing

0071-9999-17-027-L03-P (1.0 credit hours, 0.10 CEU*)

There has been a great deal of attention in the media over the prices of prescription drugs. Drug manufacturers receive most of that attention but pharmacy benefit management companies (PBMs) and others in the chain of distribution receive their share. Pricing is a very complicated subject with unknowns at every turn. In this session, we will present the historical development of prescription drug pricing including but not limited to the cash system, along with the genesis of dispensing fees, rebates and discounts, including the birth of the PBM industry and the evolution of tiered formularies with attendant cost containment features. We will cover the changes in aggregate prescription drug prices and annual increases over time, in the United States, and will address generally pricing in other developed countries especially those in Europe. We will address the high cost therapies and methods to allow patient access to them (e.g. Prescription Assistance programs and copay foundations). We will also address the relevant regulations and policies used by the federal government and states to administer Medicaid and Medicare while controlling costs. Finally, we will address 340B programs and their development and implementation.

Francis Palumbo, PhD, JD, University of Maryland; Lee Rosebush, PharnD, MS, MBA, JD, Baker & Hostetler

6:30 p.m. to 8:30 p.m. **Casual Dinner**

Saturday, November 4, 2017

8:00 a.m. to 9:00 a.m.

What's Coming Down the Pipeline: State Legislative and Regulatory Trends that impact the Practice of Pharmacy

0071-9999-17-028-L03-P (1.0 credit hours, 0.10 CEU*)

This presentation will provide examples of current proposed and recently enacted legislative and regulatory trends across the states that are being used to address specific problems in the pharmacy industry, including prescription drug abuse, medication interaction notifications and reimbursement.

Laura Carpenter, JD, RPh, LLM, Bula; Melissa Hornberg, JD, Bula

9:00 a.m. to 10:00 a.m.

Marijuana Regulation and Implementation Challenges

0071-9999-17-029-L03-P (1.0 credit hours, 0.10 CEU*)

The status of marijuana regulation in the US encompasses a confusing federal policy of criminalization, and a patchwork of state legislation; twenty-eight states have passed medical marijuana laws, while eight states and the District of Columbia have approved recreational use.

Federally, marijuana falls within schedule I of the Controlled Substances Act of 1970, having been determined to have "a high potential for abuse" with "no currently accepted medical use in treatment in the United States" and "a lack of accepted safety for use of the drug or other substance under medical supervision." (21 U.S.C. 812(b)(1)). However, the FDA states that it is willing to accept studies indicating safety and effectiveness of cannabis for medical purposes, and the Department of Justice currently does not prosecute conduct in compliance with state laws. Recent statements from a new administration reflect the potential for a new federal policy or approach may be forthcoming.

Meanwhile, as a result of state electoral victories, marijuana possession, use and regulation is treated very differently in various states. Implementation of these laws has not been simple, and issues consistently arise regarding physician professional conduct and first amendment protections for prescribing and treating patients; guidelines for production and sale of marijuana; and conflict of law resolution involving supremacy clause considerations.

Livia Cook, JD, The University of Arizona; Elizabeth Hall-Lipsy, JD, MPH, The University of Arizona

10:00 a.m. to 10:15 a.m. **BREAK**

10:15 a.m. to 12:15 p.m.

Case Law Update

0071-9999-17-030-L03-P (2.0 credit hours, 0.20 CEU*)

This annual summary provides pharmacists, compliance personnel, and attorneys an overview of the most important court decisions, lawsuits, and settlements from October 2016 to present. Presenters will address a variety of industry-specific civil and criminal liability issues, including pharmacy employment claims, False Claims Act cases and settlements, managed care and antitrust actions, state regulatory boards' authority to discipline licensees, and more.

Roger Morris, RPh, JD, Quarles & Brady LLP; William Stilling, RPh, MS, JD, Kimball Legal

2:00 p.m. to 3:15 p.m.

Pharmacy Law Educators: Results of the Law and Ethics Benchmarking Survey Coverage

0071-9999-17-031-L03-P (1.25 credit hours, 0.15 CEU*)

We will be reviewing the results of a survey sent to all U.S. colleges and schools of pharmacy which provides characteristics of pharmacy law and ethics courses. The results provide a glimpse into how institutions deliver pharmacy law and ethics education including: instructor characteristics, topics covered, assessment strategies, resources used, and several other areas.

Erin Albert, RPh, MBA, PharmD, JD, PAHM, Myers and Stauffer, Pharmacy Podcast; Geoffrey Mospan, PharmD, BCPS, Wingate University School of Pharmacy

3:15 p.m. to 4:30 p.m.

Pharmacy Law Educators: Standards Update and How to Prepare Students for the MPJE/CPJE, Discussion on MPJE study strategic methods and pedagogy, The Pharmacy Law Case Law Compendium - how to use it in the classroom

0071-9999-17-032-L03-P (1.25 credit hours, 0.15 CEU*)

Panel members will lead an interactive discussion regarding the structure of the MPJE and CPJE, best study methods and how to best prepare student pharmacists for examination.

Shannon Panther, PharmD, BCACP, Washington State University; Fred Brinkley, Jr., RPh, MBA, University of Texas at Austin College of Pharmacy; Robert Stein, PharmD, JD, Keck Graduate Institute School of Pharmacy

Sunday, November 5, 2017

7:00 a.m. to 12:00 p.m. **Registration Open**

7:00 a.m. to 8:00 a.m. **Breakfast**

8:00 a.m. to 9:00 a.m.

The Intersection of Specialty Pharmacy and the Law

0071-9999-17-033-L03-P (1.0 credit hours, 0.10 CEU*)

This session will highlight the specialty pharmacy business model that drives unique legal issues. It will then provide a high level overview of the primary laws at issue. The speakers will apply the law to the unique specialty pharmacy business aspects highlighting the issues in specialty pharmacy that are not typical in the retail pharmacy space.

Abby Kaplan, JD General Counsel and Chief Compliance Officer, Avella Specialty Pharmacy; Shannon Wiley, JD, Bass Berry & Sims

9:00 a.m. to 10:00 a.m.

Import at Your Own Risk: Why Canadian Pharmacies Are Not the Answer

0071-9999-17-034-L03-P (1.0 credit hours, 0.10 CEU*)

On any given day, thousands of websites claim to be selling Health Canada-approved medicines to consumers online. One in four Americans buy medicines online according to the US FDA, yet 96% of the websites pushing medicine are operating illegally with many of those sites feigning legitimacy using the words "Canada" or "Canadian pharmacy." Unfortunately, this is rarely true. These sites often sell counterfeit, unapproved and otherwise illegal medicines to patients, operate without the required pharmacy license, and sell prescription medicines without a prescription. Instead, Canadian drug sellers sell US consumers medicines from India, Turkey, and Southeastern Asia, feeding a bifurcated supply chain filled with counterfeit medications containing toxins, adulterants, or an unsafe level of drug. This patient safety issue has been thrust into the spotlight, given the introduction of federal legislation permitting online medicine sales from Canadian pharmacies. This issue raises important legal and safety concerns, especially when coupled with the growing opioid epidemic, rising cost of drugs, and changes in payment and coverage that threaten to limit patient access to medicines through traditional pharmacies. Speakers from the Alliance for Safe Online Pharmacies (ASOP Global), an international nonprofit organization dedicated to protecting patient safety online, and the National Association of Boards of Pharmacy propose to discuss recent federal legislative and administrative efforts that would encourage US patients to buy "Canadian" medicine online. Bios below. During their presentation, Libby, John, and Marty will educate on new legal and regulatory developments, share new data on Internet pharmacy studies, and provide tips to lawyers whose pharmacy and pharmacist clients may be impacted by the trend of internet sales of medicines.

Libby Baney, JD, Alliance for Safe Online Pharmacies; Ronald Guse, National Association of Boards of Pharmacy; John Hertig, PharmD, MS, CPPS, Purdue University College of Pharmacy

10:20 a.m. to 11:20 a.m.

Discipline Sanctions for Dispensing Errors: Impediment or Aid to Patient Safety?

0071-9999-17-035-L03-P (1.0 credit hours, 0.10 CEU*)

Pharmacists are held to an absolute standard of perfection for dispensing prescriptions correctly, yet every dispensing pharmacist misdispenses drugs from time-to-time. This presentation will explore: (i) how states address single dispensing errors; (ii) factors that increase the likelihood that an error will be reported to a board of pharmacy; (iii) comparison of laws and policies governing discipline for errors between pharmacists and other health care professionals; (iv) the continuing evolution of segmented and central fill pharmacy systems; (v) allocation of fault within segmented and central fill dispensing systems; (vi) the effect of state disciplinary laws on workload balancing and other new systems designed to increase patient safety; (vii) the application of a just culture model to pharmacy errors; (viii) the use of disciplinary proceedings by plaintiffs' counsel and effect on such proceedings on civil litigation; (ix) how to address public and political concerns and pressure about pharmacist errors; and (x) suggestions for error prevention without licensure sanctions. The presenters expect that this program will engender a lively discussion among attendees and invite attendees to contribute their insights into these issues.

William Stilling, RPh, MS, JD, Parsons Behle & Latimer; Michael Simko, RPh, JD, Walgreen Co.

*Activity Type = Knowledge